Exhibit A

[redacted]

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC., and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant and Counter-Plaintiffs v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff and Counter-Defendants.	

REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE PURSUANT TO THE HAGUE CONVENTION ON THE TAKING OF EVIDENCE ABROAD IN CIVIL OR COMMERCIAL MATTERS CONCLUDED 18 MARCH 1970

To: The Competent Authority of Australia
Private International and Commercial Law Section
Australian Government
Attorney-General's Department
Robert Garran Offices
3-5 National Circuit
BARTON ACT 2600
Australia

From: The Honorable Gregory B. Williams
The United States District Court for the District of Delaware
844 North King Street
Wilmington, Delaware 19801
United States of America

Re: Request for Judicial Assistance Pursuant to the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters Concluded 18 March 1970

I. Information Provided Pursuant to Convention Article 3(a).

A. Requesting Court

In conformity with Article 3 of the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, concluded 18 March 1970 (the "Convention"), the United States District Court for the District of Delaware (United States District Judge Gregory B. Williams presiding), respectfully requests the assistance of your honorable courts with regard to the matters set forth below

B. Full title of action

The Full title of the action in which international judicial assistance is requested is:

Nippon Shinyaku Co., Ltd. et al. v. Sarepta Therapeutics, Inc., et al.

The case number of the action in the United States District Court for the District of Delaware is Civil Action Number 21-1015-GBW.

II. Information Provided Pursuant to Convention Article 3(b).

A. Names of the parties to the action

The plaintiff and counterclaim-defendant in this action is Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku"). Nippon Shinyaku is a Japanese corporation organized under the laws of Japan with a principal place of business at 14 Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550 Japan. Nippon Shinyaku is represented in this action by:

Amy M. Dudash
1201 N. Market Street
Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001

Eric Kraeutler
Alison Patitucci
MORGAN, LEWIS & BOCKIUS LLP

Amanda S. Williamson
Christopher J. Betti
Krista V. Venegas
Wan-Shon Lo
Maria E. Doukas
Zachary Miller
Guylaine Haché
Michael T. Sikora
MORGAN, LEWIS & BOCKIUS LLP
110 N. Wacker Drive, Ste 2800

1701 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001

Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001

Nippon Shinyaku's associated Counsel in Australia is Simone Mitchell at the law firm MinterEllison, located at Level 40, Governor Macquarie Tower, 1 Farrer Place, Sydney 2000 Australia.

The defendant and counterclaim plaintiff in this action is Sarepta Therapeutics, Inc. ("Sarepta"). Sarepta is a corporation organized and existing under the laws of Delaware, United States with a principal place of business at 215 First Street, Cambridge, MA 02142. Sarepta is represented by:

Jack B. Blumenfeld
Megan Elizabeth Dellinger
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200

William B. Raich
Michael J. Flibbert
Yoonhee Kim
Yoonjin Lee
FINNEGAN, HENDERSON, FARABOW, GARRET & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Charles E. Lipsey
J. Derek McCorquindale
Ryan P. O'Quinn
FINNEGAN, HENDERSON, FARABOW, GARRET & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190-6023
(571) 203-2700

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW, GARRET & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600

The counterclaim plaintiff in this action is the University of Western Australia, Inc. ("UWA"). UWA is a public research university organized and existing under the laws of Australia with its main campus and offices located at 35 Stirling Highway, Crawley, Perth Western Australia 6009. UWA is represented by:

Jack B. Blumenfeld
Megan Elizabeth Dellinger
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200

Charles E. Lipsey
J. Derek McCorquindale
Ryan P. O'Quinn
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1875 Explorer Street, Suite 800
Reston, VA 20190-6023
(571) 203-2700

William B. Raich
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FINNEGAN, HENDERSON, FARABOW, GARRET & DUNNER, LLP
901 New York Avenue, NW
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(202) 408-4000

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW, GARRET & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600

The counterclaim defendant in this action is NS Pharma, Inc. ("NS Pharma"). NS Pharma is a corporation organized and existing under the laws of Delaware, United States with a principal place of business at 140 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. NS Pharma is represented by:

Amy M. Dudash
1201 N. Market Street
Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001

Eric Kraeutler
Alison Patitucci
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
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Telephone: 215.693.5000
Fax: 215.963.5001

Amanda S. Williamson
Christopher J. Betti
Krista V. Venegas
Wan-Shon Lo
Maria E. Doukas
Zachary Miller
Guylaine Haché
Michael T. Sikora
MORGAN, LEWIS & BOCKIUS LLP
110 N. Wacker Drive, Ste 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001

III. Information Provided Pursuant to Convention Article 3(c).

A. Nature and Summary of the Proceedings.

The Action is a patent infringement case involving antisense oligonucleotide treatments for Duchenne's muscular dystrophy ("DMD"). Nippon Shinyaku and Sarepta are direct competitors that each provide antisense oligonucleotide-based therapies for the treatment of DMD. Sarepta and Nippon Shinyaku are the only companies with approval from the United States Food & Drug Administration to market oligonucleotide therapies that induce exon 53-skipping for the treatment of DMD for patients in need thereof. Sarepta's product is marketed under the name VYONDYS 53, and Nippon Shinyaku's product is marketed under the name VILTEPSO®.

Nippon Shinyaku owns U.S. Patent Numbers 9,708,361, 10,385,092, 10,407,461, 10,487,106, 10,647,741, 10,662,217, and 10,683,322 (the "NS Patents"), relating the exon 53-skipping treatments. UWA owns U.S. Patent Numbers 9,994,851, 10,227,590, and 10,266,827 (the "UWA Patents"). Sarepta is the exclusive licensee of the UWA Patents.

On July 13, 2021, Nippon Shinyaku filed this civil action against Sarepta in the United States District Court for the District of Delaware. Nippon Shinyaku alleges that Sarepta's manufacture, use, and sale of VYONDYS 53 infringes claims of the NS Patents and seeks a declaratory judgment of invalidity of the UWA Patents. (Second Am. Compl. ¶¶ 1-3, 76-164, **Exhibit I**.) Sarepta and UWA asserted counterclaims alleging that Nippon Shinyaku and NS Pharma's manufacture, use, and sale of VILTEPSO® infringes claims of the UWA Patents and seeking a declaratory judgment of invalidity of the NS Patents (Answer ¶¶ 1-2, 26-81, **Exhibit II**). A patent infringement claim requires the patentee to prove that each and every element of its patent claim(s) may be found in an accused product that the alleged infringer makes, uses, sells, or offers to sell in the United States.

NS denies infringement and alleges that the UWA Patents are invalid. (Answer to Countercl. ¶¶ 1-2, 36-81, **Exhibit III**). In its declaratory judgment claims and its Answer, NS alleges that the UWA Patents are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 *et seq*. relating to requirements for patentability, including, without limitation, 35 U.S.C. §§ 102 (which relates to the requirement of novelty), 103 (which relates to the requirement of non-obviousness) and 112 (which relates to requirements of the patent's written specification) (*Id.*)

The UWA Patents name Stephen Donald Wilton, Sue Fletcher, and Graham McClorey as inventors. (Second Am. Compl. ¶ 49.) [redacted] While at UWA, Dr. Fletcher published numerous articles relating to antisense oligonucleotide treatments for DMD. Dr. Fletcher is also listed as an inventor of International Application No. PCT/AU2010/001520, which discloses antisense oligonucleotides for exon-skipping to treat DMD, including several antisense oligonucleotides that fall within the claimed genus of the UWA Patents.

[redacted]

The Court has set a trial date for May 13, 2024. *See* **Exhibit IV.**

IV. Information Provided Pursuant to Convention Article 3(d).

A. Evidence to be obtained.

It is necessary, for the due determination of the matters in dispute between the parties in the matter pending before the United States District Court for the District of Delaware, to obtain evidence from an inventor of the UWA Patents relating to the inventive contributions of all persons involved in the conception and reduction to practice of the inventions, the timing of the conception and reduction to practice of the inventions, and their roles in the research.

Accordingly, the Court respectively requests that you cause the witness listed below, who is resident within your jurisdiction, to be subject to oral examination for use at the trial of this matter.

The Court considers that the evidence sought is directly relevant to the issues in dispute as described in the Complaint and Answer and is not pre-trial discovery within the meaning of Article 23 of the Hague Evidence Convention, that is, discovery intended to lead to relevant evidence for trial. The evidence sought is to be used—and would be admissible—in the trial in Delaware.

This letter of request is issued at the request of Nippon Shinyaku and NS Pharma.

V. Information Provided Pursuant to Convention Article 3(e).

A. Names and addresses of the witnesses.

The names and last known addresses of the witnesses from whom testimony is sought are listed below:

Sue Fletcher
[redacted]

VI. Information Provided Pursuant to Convention Article 3(f)

A. Documents to be produced by the witness

Despite being a former professor at UWA and an inventor of the UWA Patents, neither Sarepta nor UWA has produced any laboratory notebooks, emails, memos, or notes from Dr. Fletcher showing her role in exon 53-skipping research. [redacted] Therefore, the Court requests that you cause Dr. Fletcher produce:

- Any non-privileged documents relating to any work she conducted relating to developing and/or testing molecules intended to induce skipping of exon 53 of the dystrophin gene;
- Any non-privileged communications related to the design or testing of antisense oligonucleotide molecules intended to induce skipping of exon 53 of the dystrophin gene;
- Any non-privileged documents related to the drafting, filing, and prosecution of the application or applications that issued as the UWA Patents or any other U.S. applications that claim priority to such application or applications;
- A copy of any agreements governing her current or past relationship with UWA and/or Sarepta, including any employment agreements and consulting agreements.

B. Testimony to be provided by the witnesses

Dr. Fletcher is a former professor at UWA and an inventor of the UWA Patents. [redacted]

[redacted] Therefore, the Court requests that you cause Dr. Fletcher to give testimony on the following subjects:

- Facts relating to her technical background and education as they pertain to the subject matter of the UWA Patents;
- Facts relating to her employment with UWA and/or Perron Institute;
- Facts relating to the members of the Wilton and/or Fletcher laboratories at UWA and/or Perron Institute in the 2003–2012 time frame;
- Facts relating to the workflow of the Wilton and/or Fletcher laboratories at UWA and/or Perron Institute, including the assignment of projects and project management;
- Facts related to the conception, research, development, design, testing, analysis, evaluation, and/or reduction to practice of the subject matter of any claim of the UWA Patents.
- Facts related to the drafting, filing, and prosecution of the application or applications that issued as the UWA Patents or any other U.S. applications that claim priority to such application or applications.
- Facts related to work, experiments, tests, or studies relating to DMD, including the selection of exons to target, the selection of target regions or binding sites in exon 53, and the design and synthesis of antisense oligonucleotides (ASOs) including any methods or approaches used to optimize any ASO(s) for exon-skipping activity;
- Facts relating to any experiments, tests, or studies of ASOs that exhibit exon-skipping, including those that exhibit exon 53-skipping, including experimental design and analysis, discussion, or evaluation of results or data;

- Facts relating to any experiments, tests, or studies that led to any abstract, presentation or publication relating to ASOs to induce exon-skipping for the potential treatment of DMD;
- Facts relating to any experiments, tests, or studies that led to the subject matter disclosed in International Patent Application No. PCT/AU2005/000943;
- Facts relating to any experiments, tests, or studies that led to or the subject matter disclosed in International Patent Application No. PCT/AU2010/001520;
- Facts relating to [redacted]

The evidence sought with respect to each of these topics will be limited to evidence that will be adduced at trial.

In the course of the examination of the witnesses, Nippon Shinyaku and NS Pharma intend to show documents to the witnesses, all of which relate to the subject matters set forth in Section VI of this letter of request. If so ordered by the Court, Nippon Shinyaku and NS Pharma will prepare a selection of such documents for the witness to review prior to her examination

VII. Information Provided Pursuant to Convention Article 3(h)

A. Form of the examination.

The witnesses should be examined under oath. I respectfully request that you: cause the evidence of the witnesses to be reduced into writing; cause the evidence of the witnesses to be recorded on video; cause all documents produced on such examinations to be duly marked for identification; and cause copies of the documents to be made. I further request that you authenticate such examinations by the seal of your Court in such way as is in accordance with your procedure, and return the written evidence, video evidence, and documents produced to me at the following address:

Gregory B. Williams, United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street, Unit 26, Room 6124
Wilmington, DE 19801-3555, United States

VIII. Information Provided Pursuant to Convention Article 3(i)

A. Procedure.

It is respectfully requested, except to the extent that such rules are incompatible with the internal laws of Australia, that all documents requested herein be produced in accordance with the U.S. Federal Rules of Evidence, as they would apply during a trial in the United States District Court.

The testimony should be given before a fit and proper person as nominated by your Court. The witnesses should give an oath or affirmation before testifying; the testimony should be transcribed by a stenographer; and the testimony should be recorded on video by a videographer. I request that the deposition shall be taken under the Federal Rules of Civil Procedure of the United States of America, except to the extent such procedure is incompatible with the internal laws of Australia.

In addition, I request that the United States attorneys for all parties to this action should be permitted to be present in person or by video link and to conduct examination and cross-examination of the witnesses. Simone Mitchell, Australian counsel for the Nippon Shinyaku and NS Pharma, will assist in the process of securing this deposition and is nominated to make any application or motion to your Court on behalf of Nippon Shinyaku or NS Pharma that may be required, and will be present at the deposition. I request that Dr. Fletcher be permitted to be represented by her own counsel at the deposition. At the deposition, Dr. Fletcher shall be allowed

to take legal advice in order to prevent the disclosure of privileged information and to claim privileges under both the laws of the United States and those of Australia.

It is respectfully requested that the deposition be allowed to continue until completed, except that (i) the deposition not exceed seven hours on the record per day; and (ii) Requestors' examination shall not exceed a total of seven hours on the record.

B. Specification of privilege or duty to refuse to give evidence under the laws of the state of origin.

Under the laws of the United States, a party has a privilege to refuse to give evidence if the evidence discloses a confidential communication between that party and an attorney for that party that was made for the purpose of obtaining legal advice and which privilege has not been waived explicitly or implicitly. Parties also enjoy limited privileges on other grounds not relevant here, such as communications between physician and patient, psychotherapist and patient, husband and wife, or clergy and penitent. The laws of the United States also recognize a privilege against self-incrimination.

Outside the strict area of privilege, certain limited immunities are available that may place restrictions on the giving of evidence, such as the limited protection against the disclosure of documents and tangible things prepared in anticipation of litigation or for trial by or for a party or a party's representative.

C. Details

It is requested that the documents be produced at the offices of MinterEllison, Level 4, Allendale Square, 77 St Georges Terrace, Perth 6000 Australia, or at a location mutually agreed upon by the parties, on dates to be agreed between the parties, but in any event no later than 10 days before the deposition.

It is requested that the examination take place at the offices of MinterEllison, Level 4, Allendale Square, 77 St Georges Terrace, Perth 6000 Australia, or at a location mutually agreed upon by the parties, on dates to be agreed between the parties, the witnesses and the examiners appointed by your Courts or, failing agreement, as nominated by the examiners appointed by your Courts, but in any event no later than August 25, 2023.

Any correspondence regarding this Letter of Request should be sent to the parties' attorneys (including Nippon Shinyaku and NS Pharma's Australian attorneys – MinterEllison).

D. Fees and Costs

The fees and costs incurred which are reimbursable under the second paragraph of Article 14 or under Article 26 of the Convention will be borne by Nippon Shinyaku and NS Pharma.

IX. Conclusion.

This Court expresses its appreciation for this assistance, states that the courts of the United States are authorized by Section 1782 of Title 28 of the United States Code to extend similar assistances to the Courts of Australia, and is prepared to provide reciprocal assistance to the Courts of Australia in any circumstances in which it may be required

This Court extends to the judicial authorities of Australia the assurances of the highest consideration.

Date of request:_____, 2023

Signature and Seal of the requesting authority:

_____

The Honorable Gregory B. Williams
United States District Court Judge
United States District Court for the District of Delaware
Wilmington, Delaware, U.S.A.

Exhibit I

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., a Japanese company; Plaintiff, v. SAREPTA THERAPEUTICS, INC., a Delaware corporation Defendant.	)	CIVIL ACTION NO. 21-1015 (LPS)

SECOND AMENDED COMPLAINT FOR BREACH OF CONTRACT, DECLARATORY JUDGEMENT OF PATENT INVALIDITY, AND PATENT INFRINGEMENT

Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku" or "Plaintiff") by and through its undersigned attorneys, alleges as follows for its Second Amended Complaint for Breach of Contract, Declaratory Judgment of Patent Invalidity, and Patent Infringement against Sarepta Therapeutics, Inc. ("Sarepta" or "Defendant"):

Nature of the Action

1. Nippon Shinyaku asserts a claim for breach of contract. This claim arises out of Sarepta's breach of its Mutual Confidentiality Agreement ("MCA," D.I. 2-1) with Nippon Shinyaku. Sarepta breached the MCA by filing seven petitions for *Inter Partes Review* (collectively, the "IPR Petitions") with the Patent Trial and Appeal Board ("PTAB") at the United States Patent and Trademark Office ("USPTO").[1] The IPR Petitions seek to invalidate U.S. Patent

[1] Sarepta's IPR Petitions were filed with the following case numbers: (i) IPR2021-01134; (ii) IPR2021-01135; (iii) IPR2021-01136; (iv) IPR2021-01137; (v) IPR2021-01138; (vi) IPR2021-01139; and (vii) IPR2021-01140.

Nos. 9,708,361 ("'361 Patent," D.I. 2-2); 10,385,092 ("'092 Patent," D.I. 2-3); 10,407,461 ("'461 Patent," D.I. 2-4); 10,487,106 ("'106 Patent," D.I. 2-5); 10,647,741 ("'741 Patent, D.I. 2-6); 10,662,217 ("'217 Patent, D.I. 2-7); and 10,683,322 ("'322 Patent," D.I. 2-8). Sarepta's filing of the IPR Petitions directly contravenes the MCA's forum selection clause, which requires that Sarepta and Nippon Shinyaku bring any such patent challenges in the United States District Court for the District of Delaware.

2. Nippon Shinyaku also asserts claims for declaratory judgment of invalidity of United States Patent Nos. 9,994,851 ("'851 Patent," D.I. 2-9), 10,227,590 ("'590 Patent," D.I. 2-10), and 10,266,827 ("'827 Patent," D.I. 2-11) (collectively, the "Western Australia Patents" or "UWA Patents"). Upon information and belief, Sarepta is the exclusive licensee with assertion rights for the UWA Patents.

3. Nippon Shinyaku further asserts claims for patent infringement of the '361 Patent, '092 Patent, '461 Patent, '106 Patent, '741 Patent, '217 Patent, and '322 Patent (collectively, the "NS Patents"). These claims arise out of Sarepta's manufacture, use, sale, offers to sell within the United States, and/or importation into the United States of its morpholino antisense oligomer ("ASO") that induces skipping of exon 53 of the human dystrophin gene to treat Duchenne Muscular Dystrophy ("DMD") and Sarepta's intentional encouragement of physicians to administer this ASO to patients. Sarepta developed this ASO under the names "SRP-4053" and "golodirsen" and markets it in the United States as VYONDYS 53.

Parties

4. Nippon Shinyaku is a Japanese company with a principal place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

5. Nippon Shinyaku is an innovative pharmaceutical company whose mission is to "help people lead healthier, happier lives." It accomplishes this mission by developing and supplying unique and high-quality therapies that are safe and highly effective relative to other drugs and that contribute to a better quality of life for patients.

6. Nippon Shinyaku not only serves general patient populations through its various drugs for urological diseases, hematology, gynecology, and otorhinolaryngology—but it also seeks to provide meaningful relief for patients suffering from rare, intractable diseases like DMD.

7. Upon information and belief, Sarepta is a Delaware corporation with its principal place of business at 215 First Street, Cambridge, Massachusetts 02142.

Jurisdiction and Venue

8. Nippon Shinyaku's claim for breach of contract arises under Delaware state law. This Court has subject matter jurisdiction over this breach of contract claim under 28 U.S.C. §§ 1332(a) and 1367(a).

9. Nippon Shinyaku's claims for declaratory judgment of invalidity of the UWA Patents arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq.

10. This Court has subject-matter jurisdiction over these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Nippon Shinyaku and Sarepta are direct competitors that each provide antisense oligonucleotide-based therapies for the treatment of DMD. Sarepta and Nippon Shinyaku are the only companies with FDA clearance to market oligonucleotide therapies that induce exon 53-skipping for the treatment of DMD for patients in need thereof. Sarepta's product is marketed

under the name VYONDYS 53, and Nippon Shinyaku's product is marketed under the name VILTEPSO®.

12. In 2013 and 2015, the University of Western Australia ("UWA") obtained two patents directed towards antisense oligonucleotide-based therapies for the treatment of DMD: U.S. Patent No. 8,455,636 ("the '636 Patent) (D.I. 39-1) and 9,024,007 ("the '007 Patent) (D.I. 39-2). Each of these patents' claims encompasses Sarepta's VYONDYS 53 but fails to encompass Nippon Shinyaku's VILTEPSO®.

13. On January 16, 2017, FDA granted Orphan Drug Designation to Nippon Shinyaku for its antisense oligonucleotide-based therapy that would eventually be approved and marketed under the name VILTEPSO®. D.I. 39-3. Subsequent to FDA granting this Orphan Drug Designation, applications for the three UWA Patents were filed with the United States Patent and Trademark Office ("USPTO"). These UWA Patents, unlike the '636 Patent and '007 Patent, included new claims aimed at capturing VILTEPSO®. Sarepta has listed the UWA Patents on its FDA Orange Book listing for VYONDYS 53. NDA applicants "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). In the Orange Book, Sarepta lists a patent expiry date for the UWA Patents of June 28, 2025 but are seeking a significant patent term extension that would extend their expiry date at least with respect to claims covering VYONDYS 53®.

14. Sarepta and Nippon Shinyaku have engaged in non-confidential communications regarding the licensing of Serapta's UWA Patents. Sarepta has taken affirmative action toward Nippon Shinyaku's VILTEPSO® product.

15. After some initial discussion, a meeting occurred on or about January 13, 2020, during which Sarepta's VYONDYS 53 product and Nippon Shinyaku's VILTEPSO® product were discussed. The meeting was attended by at least Mr. Matthew Gall of Sarepta and Mr. Masaya Toda of Nippon Shinyaku. As a result of that January 13, 2020, meeting, the Parties agreed to engage in negotiations concerning the Parties' patent portfolios, including Sarepta's UWA Patents. Sarepta requested that further discussions be held under a confidentiality agreement, and Nippon Shinyaku understood that these discussions would include discussions of licensing Sarepta's UWA Patents to avoid litigation.

16. During the same timeframe and before January 28, 2020, Chris Verni, Sarepta's Chief IP counsel sought out Nippon Shinyaku's outside counsel while they were attending a conference for the Association of Corporate Patent Counsel. Mr. Verni raised concerns about the possibility of litigation between the Parties and encouraged discussions as a means to avoid litigation.

17. After June 1, 2021, Sarepta and Nippon Shinyaku were no longer engaged in confidential discussions relating to their respective patent portfolios or products. Sarepta had not granted a license or covenant not to sue to Nippon Shinyaku for the UWA Patents, and Nippon Shinyaku had not granted a license or covenant not to sue Sarepta to the NS Patents.

18. On July 6, 2021, Mr. Joe Zenkus, Senior Vice President at Sarepta, emailed Mr. Masaya Toda at Nippon Shinyaku regarding Sarepta's filing of the IPR Petitions to invalidate the NS Patents. D.I. 39-4. In his email, Mr. Zenkus notes that "Sarepta was compelled to file the IPRs against the seven patents that NS obtained in the US to seek to cover Vyondys 53 [the NS Patents]."

19. He further notes that "Sarepta is prepared to continue on with the IPRs and ***pursue other actions deemed necessary for it to protect its rights***." Mr. Zenkus' statement was neither an admission of liability nor the amount of liability as to the NS Patents, but rather a present threat that Sarepta will assert its UWA Patents against Nippon Shinyaku. This communication was not subject to any confidentiality obligation. Under these circumstances, and as a result of at least these communications, Nippon Shinyaku was and remains under a reasonable apprehension that Sarepta would file a lawsuit asserting the UWA Patents against Nippon Shinyaku's U.S. sales of its VILTEPSO® product and threatening Nippon Shinyaku's goal to serving DMD patients and growing its U.S. market for this product. Nippon Shinyaku contends that no license is required from Sarepta under the UWA Patents for its continued sale of VILTEPSO®, and Nippon Shinyaku seeks to be free of risk of a claim for damages or other remedies by Sarepta in the future. Thus, a controversy existed when Nippon filed its original complaint in this matter on July 13, 2021 and continues to exist between the parties as to the non-infringement and invalidity of the UWA Patents.[2]

20. On September 8, 2021, Nippon Shinyaku sent Sarepta a covenant not to sue Nippon Shinyaku for infringement of the UWA Patents due to Nippon Shinyaku's making, using, offering to sell, selling, and/or importing into the United States VILTEPSO® and requested that Sarepta

[2] In order to ensure that this case can promptly move forward (and eliminating another basis for Sarepta purportedly delaying this case), NS will proceed on the Claims noted above and reserves the right to plead the defense of non-infringement in response to a Sarepta claim of infringement.

immediately execute that agreement. Despite having adequate time to consider Nippon Shinyaku's offer, Sarepta has failed to respond or execute the convent not to sue.

21. Nippon Shinyaku's claims for patent infringement of the NS Patents arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq.

22. The amount in controversy exceeds $75,000, exclusive of interest and costs.

23. Upon information and belief, Sarepta markets and sells ASOs, including VYONDYS 53. Upon information and belief, Sarepta currently manufactures, sells and offers to sell VYONDYS 53 throughout the United States and in this District.

24. This Court has subject-matter jurisdiction over these claims for patent infringement under 28 U.S.C. §§ 1331 and 1338(a).

25. This Court has personal jurisdiction over Sarepta, a Delaware corporation, at least because Sarepta resides in this District and has consented to this Court's jurisdiction. D.I. 2-1, Section 10.

26. Venue is proper under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) at least because Sarepta, a Delaware corporation, resides in this District and because Sarepta has consented to this venue. D.I. 2-1, Section 10.

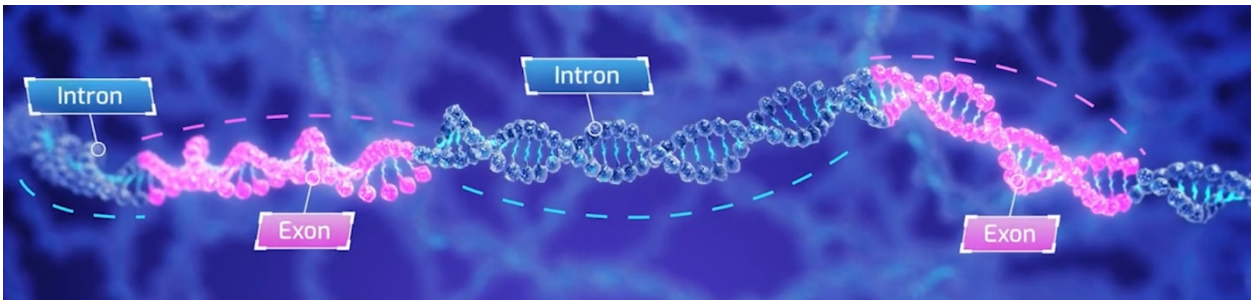
Duchenne Muscular Dystrophy

27. DMD is a severe X chromosome-linked genetic disorder that predominantly affects young boys. Approximately one in every 3,500 boys suffer from DMD, which is the most common form of hereditary progressive muscular dystrophy. Children with DMD suffer muscle weakness as early as age four and progressively lose muscle function and quality-of-life. By age twelve, DMD patients typically lose ambulatory function and are confined to wheelchairs. Body-wide muscle loss also contributes to numerous other health complications throughout patients' lives.

As a result of DMD-induced cardiac and/or respiratory deficiencies, most patients suffering from DMD do not live past their twenties.

28. DMD is caused by mutation(s) in the dystrophin gene, which codes for the dystrophin protein. The dystrophin protein contributes to cell membrane stability in muscle cells and makes muscle cells less fragile. In DMD patients, however, the mutated dystrophin gene causes significant under-expression of the dystrophin protein, leaving them with insufficient levels of dystrophin protein to maintain their muscle cells.

29. The dystrophin gene is long, spanning approximately 2.2 million nucleotide pairs and comprising 79 exons (regions of nucleotides that code for the 3,685 amino acids making up the dystrophin protein) interspersed with introns (regions that do not code for the dystrophin protein).



30. In a non-DMD patient, cells generally prepare dystrophin protein from the gene as follows:

> **Transcription:** The dystrophin gene (DNA) is transcribed into an RNA strand containing both exons and introns known as "pre-mRNA."
>
> **Splicing:** Cellular machinery removes intron sequences and "splices" the exons together to form mRNA.
>
> **Translation:** Cellular machinery "reads" the mRNA strand three nucleotides at a time to determine and assemble the amino acid sequence for dystrophin.

31. DMD typically results when a mutation shifts the amino acid reading frame, producing a non-functional dystrophin protein. As show below, even a single nucleotide deletion can alter how the cellular machinery reads the remainder of the mRNA sequence (and consequently how the cell assembles the dystrophin protein).

Original: ABC ABC ABC ABC ABC ABC

Mutation: ABA BCA BCA BCA BCA BCA

32. Mutations that preserve the original amino acid reading frame may produce a partially functional dystrophin protein with exon deletions. This typically causes a less-severe condition known as Becker Muscular Dystrophy ("BMD"). Like DMD, BMD patients suffer from muscle weakness and atrophy, but they experience milder and slower disease progression. Many BMD patients do not experience symptoms of disease onset until they are well into adulthood.

33. There is no cure for DMD. Care providers have traditionally prescribed corticosteroids to promote muscle strength and delay disease progression. Such treatment carries substantial risks of side-effects, including weight gain and weakened bones, and does not stop the progress of the disease.

Exon-Skipping Antisense Oligomers as a Therapeutic Option

34. Antisense oligomers ("ASOs") are short nucleic acid strands that modify splice patterns to address the genetic defects responsible for DMD. ASOs bind with particular nucleotide sequences in or near the exon of interest on the pre-mRNA strand. ASOs interfere with the ordinary splicing process, causing the cell to "skip" the mutated exon(s) when preparing mRNA.

35. By "skipping" the mutated exons, ASOs cause cells to prepare shorter-than-normal mRNA while preserving the original amino acid reading frame. As a result, patients' cells produce partially functional—rather than non-functional—protein. Applied to DMD, these treatments

effectively convert a DMD patient into a BMD patient, providing substantially better quality-of-life.

Nippon Shinyaku's Development of Exon 53 Skipping Oligomers

36. Recognizing the severe impact of DMD, Nippon Shinyaku began developing exon skipping therapies for DMD. Nippon Shinyaku focused first on therapies targeting exon 53, which would provide a treatment for approximately 8% of all DMD patients. Nippon Shinyaku ultimately determined that a 21 nucleobase (also call a 21mer) sequence targeted to the 36th to 56th nucleotides from the 5' end of exon 53 (H53_36-56) exhibited superior exon skipping.

37. On September 1, 2010, Nippon Shinyaku and National Center of Neurology and Psychiatry ("NCNP") filed Japanese Patent App. No. 2010-196032, which described their discoveries.

38. Nippon Shinyaku has since continued its development of the 21mer ASO—now known as VILTEPSO®—and secured approval in both Japan and the United States for the use of VILTEPSO® in treating DMD. While clinical trials are ongoing, initial results are promising. "[D]ystrophin levels increased, on average, from 0.6% of normal at baseline to 5.9% of normal at week 25."[3] And VILTEPSO® patients did not experience kidney toxicity, a side effect the United States Food & Drug Administration ("FDA") reported for other ASOs. *Id.*

[3] FOOD & DRUG ADMIN., *FDA Approves Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation*, (Aug. 12, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last accessed July 8, 2021).

The NS Patents-In-Suit

39. On July 18, 2017, the '361 Patent, entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '361 Patent is fully maintained, valid, and enforceable. A copy of the '361 Patent is found at D.I. 2-2.

40. On August 20, 2019, the '092 Patent, entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '092 Patent is fully maintained, valid, and enforceable. A copy of the '092 Patent is found at D.I. 2-3.

41. On September 10, 2019, the '461 Patent entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '461 Patent is fully maintained and valid and enforceable. A copy of the '461 Patent is found at D.I. 2-4.

42. On November 26, 2019, the '106 Patent entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '106 Patent is fully maintained and valid and enforceable. A copy of the '106 Patent is found at D.I. 2-5.

43. On May 12, 2020, the '741 Patent entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '741 Patent is fully maintained and valid and enforceable. A copy of the '741 Patent is found at D.I. 2-6.

44. On May 26, 2020, the '217 Patent entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '217 Patent is fully maintained and valid and enforceable. A copy of the '217 Patent is found at D.I. 2-7.

45. On June 16, 2020, the '322 Patent entitled "Antisense Nucleic Acids," issued to Nippon Shinyaku and NCNP as assignees with named inventors Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. The '322 Patent is fully maintained and valid and enforceable. A copy of the '322 Patent is found at D.I. 2-8.

46. By virtue of a license agreement with NCNP, Nippon Shinyaku holds the exclusive assertion rights for the NS Patents. Specifically, the License Agreement at Art. 3(2) (Third Party Patent Infringement Lawsuit) provides that (i) Nippon Shinyaku shall have an ***exclusive right*** to file suit against third party infringers of the NS Patents and (ii) NCNP has no rights whatsoever to initiate patent infringement suits based on the NS Patents against third party infringers. D.I. 39-5.

47. Because NCNP relinquished all rights to pursue infringement allegations relating to the NS Patents against third party infringers to Nippon Shinyaku, NCNP is not a required party under Fed. R. Civ. P. 19(a). As Nippon Shinyaku holds the exclusive right to bring infringement allegations against third party infringers for infringement of the NS Patents, the court can "accord complete relief among existing parties" without NCNP being a party to the litigation. *See* Fed. R. Civ. P. 19(a)(1)(A). Additionally, as NCNP retains no rights to assert patent infringement against third party infringers, there is no risk of Sarepta "incurring double, multiple, or otherwise inconsistent obligations" if NCNP is not a party to this litigation. *See* Fed. R. Civ. P. 19(a)(1)(B)(ii).

48. Additionally, even if NCNP is deemed a required party under Fed. R. Civ. P. 19(a), it would not be an indispensable party such that the court cannot in equity and good conscience proceed among the existing parties. *See* Fed. R. Civ. P. 19(b). As stated in paragraph 47, NCNP retains no rights to bring allegations of infringement of the NS Patents against third party infringers. Thus, there is no prejudice to NCNP by not being joined to this case nor is there prejudice to Sarepta in that it could be subjected to multiple infringement suits relating to the NS Patents.

The UWA Patents

49. On June 12, 2018, the ’851 Patent entitled “Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof” issued to the University of Western Australia (“UWA”) as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the ’851 Patent.

50. On March 12, 2019, the ’590 Patent entitled “Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof” issued to UWA as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the ’590 Patent.

51. On April 23, 2019, the ’827 Patent entitled “Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof” issued to The UWA as assignees with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. On information and belief, Sarepta holds exclusive assertion rights of the ’827 Patent.

Sarepta's Infringing Product

52. Upon information and belief, Sarepta's product, VYONDYS 53, is a 25mer ASO that is 100% complementary, according to Watson-Crick base pairing, to the 36th to 60th nucleotides from the 5' end of exon 53 of human dystrophin pre-mRNA and hybridizes with the 36th to 60th nucleotides from the 5' end of exon 53 of human dystrophin pre-mRNA.[4]

53. Upon information and belief, VYONDYS 53 induces skipping of the 53rd exon in a human dystrophin pre-mRNA.

54. Upon information and belief, VYONDYS 53 is administered to patients and induces skipping of the 53rd exon of human dystrophin pre-mRNA in patients. Sarepta's label for VYONDYS 53 has encouraged—and continue to encourage—such use.

55. Upon information and belief, Sarepta copied VYONDYS 53 from Japanese Patent App. No. 2010-196032 and/or another related patent application.

56. Upon information and belief, since at least 2014, Sarepta actively researched and developed VYONDYS 53, including the development and approval of clinical trials.

57. On December 12, 2019, FDA announced it had granted accelerated approval to VYONDYS 53 for the treatment of DMD.[5]

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[4] *See, e.g.*, Highlights of Prescribing Information (Dec. 12, 2019) § 11, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211970s000lbl.pdf (last accessed July 8, 2021); Highlights of Prescribing Information (Feb. 11, 2021) § 11, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211970s002lbl.pdf (last accessed July 8, 2021).

[5] FOOD & DRUG ADMIN., *FDA Grants Accelerated Approval to First Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation*, (Dec. 12, 2019), https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-first-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last accessed July 8, 2021).

58. On December 12, 2019, Sarepta announced that "[c]ommercial distribution of VYONDYS 53 in the U.S. will commence immediately."[6]

59. Upon information and belief, since at least December 2019, Sarepta has manufactured, offered for sale, and sold VYONDYS 53 in the United States for the treatment of DMD. Sarepta's Form 10-K Annual Report for 2020 describes VYONDYS 53 as a "commercial product" and states that VYONDYS 53 was "sold in 2020 and 2019."

60. Upon information and belief, since at least December 2019, Sarepta has encouraged physicians to treat DMD patients by administering VYONDYS 53 to induce skipping of the 53rd exon of human dystrophin pre-mRNA in patients, including through its labels for VYONDYS 53.

Sarepta's Breach of the MCA

61. Sarepta and Nippon Shinyaku entered into the MCA effective June 1, 2020. D.I. 2-1.

62. Under the MCA, Sarepta and Nippon Shinyaku each covenanted "for itself, its Affiliates and their respective Representatives" not to file "Potential Actions in the United States" during the "Covenant Term." *Id.* at Section 6.1.

63. Sarepta and Nippon Shinyaku also covenanted "that all Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware." *Id.* at Section 10.

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[6] Sarepta Therapeutics, *Sarepta Therapeutics Announces FDA Approval of VYONDYS 53™ (golodirsen) Injection for the Treatment of Duchenne Muscular Dystrophy (DMD) in Patients Amenable to Skipping Exon 53*, (Dec. 12, 2019), *available at* https://investorrelations.sarepta.com/static-files/15f0244f-6c99-42de-9919-30e801049ee0 (last accessed July 8, 2021).

64. The Agreement defines "Potential Actions" as "any patent or other intellectual property disputes between NS and Sarepta, or their Affiliates, other than the EP Oppositions or JP Actions, filed with a court or administrative agency prior to or after the Effective Date in the United States, Europe, Japan or other countries in connection with the Parties' development and commercialization of therapies for Duchenne Muscular Dystrophy." *Id.* at Section 1.

65. The Agreement defines the "Covenant Term" as "the time period commencing on the Effective Date and ending upon twenty (20) days after the earlier of: (i) expiration of the Term, or (ii) the effective date of termination." *Id.*; *see also id.* at Section 7 (defining "Term" as "one (1) year following the Effective Date"—i.e. through June 1, 2021—"or, if prior to such time, until one Party provides written notification of termination to the other Party").

66. Sarepta filed its seven IPR Petitions with the PTAB on June 21, 2021, seeking to invalidate all claims of the '361 Patent, the '092 Patent, the '461 Patent, the '106 Patent, the '741 Patent, the '217 Patent, and the '322 Patent.

CLAIM I
(Breach of Contract)

67. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

68. The MCA is a valid and enforceable contract between Nippon Shinyaku and Sarepta.

69. Section 10 of the MCA states, in relevant part:

> [A]ll Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware.[7]

[7] D.I. 2-1 at § 10.

70. The MCA defines "Potential Actions" as:

> [A]ny patent or other intellectual property disputes between NS [Nippon Shinyaku] and Sarepta, or their Affiliates, other than the EP Oppositions or JP Actions, filed with a court or administrative agency prior to or after the Effective Date in the United States, Europe, Japan or other countries in connection with the Parties' development and commercialization of therapies for Duchenne Muscular Dystrophy.[8]

71. On June 21, 2021, Sarepta filed the IPR Petitions before the PTAB challenging the validity of Nippon Shinyaku's '361 Patent, '092 Patent, '461 Patent, '106 Patent, '741 Patent, '217 Patent, and '322 Patent—each of which is in connection with Nippon Shinyaku's development and commercialization of therapies for DMD.

72. By filing these IPR Petitions before the PTAB, Sarepta breached Section 10 of the MCA.

73. This breach of Section 10 of the MCA resulted in damage to Nippon Shinyaku, as it deprived Nippon Shinyaku of its bargained-for choice of forum under the MCA. This deprivation of Nippon Shinyaku's bargained-for choice of forum under the MCA cannot be translated into a monetary amount and has irreparably harmed Nippon Shinyaku. Nippon Shinyaku will be further irreparably harmed if Sarepta is not enjoined from continuing with its IPR Petitions before the PTAB.

74. Nippon Shinyaku has no adequate remedy at law.

75. Sarepta has consented to "the issuance of an injunction and to the ordering of specific performance for any breach" of the MCA. D.I. 2-1, Section 11.

[8] *Id*. at 2.

CLAIM II
(Declaratory Judgment of Invalidity of the UWA Patents)

76. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

77. Nippon Shinyaku and Sarepta are direct competitors that each provide antisense oligonucleotide-based therapies for the treatment of DMD. Sarepta and Nippon Shinyaku are the only companies with FDA clearance to market oligonucleotide therapies that induce exon 53-skipping for the treatment of DMD for patients in need thereof. Sarepta's product is marketed under the name VYONDYS 53, and Nippon Shinyaku's product is marketed under the name VILTEPSO®.

78. In 2013 and 2015, the UWA obtained two patents directed towards antisense oligonucleotide-based therapies for the treatment of DMD: the '636 Patent (D.I. 39-1) and the '007 Patent) (D.I. 39-2). Each of these patents' claims encompasses Sarepta's VYONDYS 53 but fails to encompass Nippon Shinyaku's VILTEPSO®.

79. On January 16, 2017, FDA granted Orphan Drug Designation to Nippon Shinyaku for its antisense oligonucleotide-based therapy that would eventually be approved and marketed under the name VILTEPSO®. D.I. 39-3. Subsequent to FDA granting this Orphan Drug Designation, applications for the three UWA Patents were filed with the United States Patent and Trademark Office ("USPTO"). These UWA Patents, unlike the '636 Patent and '007 Patent, included new claims aimed at capturing VILTEPSO®. Sarepta has listed the UWA Patents on its FDA Orange Book listing for VYONDYS 53. NDA applicants "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner

engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). In the Orange Book, Sarepta lists a patent expiry date for the UWA Patents of June 28, 2025 but are seeking a significant patent term extension that would extend their expiry date at least with respect to claims covering VYONDYS 53®.

80. Sarepta and Nippon Shinyaku have engaged in non-confidential communications regarding the licensing of Serapta's UWA patents. Sarepta has taken affirmative action toward Nippon Shinyaku's VILTEPSO® product.

81. After some initial discussion, a meeting occurred on or about January 13, 2020, during which Sarepta's VYONDYS 53 product and Nippon Shinyaku's VILTEPSO® product were discussed. The meeting was attended by at least Mr. Matthew Gall of Sarepta and Mr. Masaya Toda of Nippon Shinyaku. As a result of that January 13, 2020, meeting, the Parties agreed to engage in negotiations concerning the Parties' patent portfolios, including Sarepta's UWA Patents. Sarepta requested that further discussions be held under a confidentiality agreement, and Nippon Shinyaku understood that these discussions would include discussions of licensing Sarepta's UWA Patents to avoid litigation.

82. During the same timeframe and before January 28, 2020, Chris Verni, Saretpa's Chief IP counsel sought out Nippon Shinyaku's outside counsel while they were attending a conference for the Association of Corporate Patent Counsel. Mr. Verni raised concerns about the possibility of litigation between the Parties and encouraged discussions as a means to avoid litigation.

83. After June 1, 2021 Sarepta and Nippon Shinyaku were no longer engaged in confidential discussions relating to their respective patent portfolios or products. Sarepta had not granted a license or covenant not to sue to Nippon Shinyaku for the UWA Patents, and Nippon Shinyaku had not granted a license or covenant not to sue Sarepta to the NS Patents.

84. On July 6, 2021, Mr. Joe Zenkus, Senior Vice President at Sarepta, emailed Mr. Masaya Toda at Nippon Shinyaku regarding Sarepta's filing of the IPR Petitions to invalidate the NS Patents. D.I. 39-4. In his email, Mr. Zenkus notes that "Sarepta was compelled to file the IPRs against the seven patents that NS obtained in the US to seek to cover Vyondys 53 [the NS Patents]."

85. He further notes that "Sarepta is prepared to continue on with the IPRs and ***pursue other actions deemed necessary for it to protect its rights***." Mr. Zenkus' statement was neither an admission of liability nor the amount of liability as to the NS Patents, but rather a present threat that Sarepta will assert its UWA Patents against Nippon Shinyaku. This communication was not subject to any confidentiality obligation. Under these circumstances, and as a result of at least these communications, Nippon Shinyaku was and remains under a reasonable apprehension that Sarepta would file a lawsuit asserting the UWA Patents against Nippon Shinyaku's U.S. sales of its VILTEPSO® product and threatening Nippon Shinyaku's goal to serving DMD patients and growing its U.S. market for this product. Nippon Shinyaku contends that no license is required from Sarepta under the UWA Patents for its continued sale of VILTEPSO®, and Nippon Shinyaku seeks to be free of risk of a claim for damages or other remedies by Sarepta in the future. Thus, a controversy existed when Nippon filed its original complaint in this matter on July 13, 2021 and continues to exist between the parties as to the invalidity of the UWA Patents.

86. On September 8, 2021, Nippon Shinyaku sent Sarepta a covenant not to sue Nippon Shinyaku for infringement of the UWA Patents due to Nippon Shinyaku's making, using, offering to sell, selling, and/or importing into the United States VILTEPSO® and requested that Sarepta immediately execute that agreement. Despite having adequate time to consider Nippon Shinyaku's offer, Sarepta has failed to respond or execute the convent not to sue.

87. The claims of the UWA Patents are invalid for failing to comply with the conditions and requirements of the patent laws of the United States, including, specifically and without limitation, 35 U.S.C. §§ 102, 103, and 112, and the rules, regulations, and laws pertaining thereto.

88. For example, the UWA Patents are invalid under 35 U.S.C. § 103 in light of at least the following prior art, either alone or in combination:

U.S. Patent No. 6,653,467 B1 to Matsuo;

PCT Pub. No. WO 2002/024906 A1 to Van Ommen et al.;

PCT Pub. No. WO 2004/083432 A1 to Van Ommen et al.;

European Patent App. No. 1 568 769 A1 to Matsuo;

Errington, et al., 5 J. GENE MED. 518 (2003);

Morita et al., 11 BIORGANIC & MED. CHEM. 2211 (2003);

Summerton, 10 LTRS. IN PEPTIDE SCI. 215 (2003);

Summerton & Weller, 7 ANTISENSE & NUCLEIC ACID DRUG DEV. 187 (1997).

89. The UWA Patents are also invalid under the written description requirement of 35 U.S.C. § 112. For example, the inventors of the UWA Patents possessed, at most, only a very small number of ASOs, which are reported to display only a minimal amount of exon-skipping activity and none that meet each element for any independent claim. Thus, the ASOs within the inventors' possession are insufficient to support the broad genus of the claims.

90. The UWA Patents are also invalid under the enablement requirement of 35 U.S.C. § 112. For example, the UWA Patents do not reasonably inform a person of skill in the art how to determine whether a given ASO of "20 to 31 bases" with "at least 12 consecutive bases of . . . SEQ ID NO: 195" induces skipping of exon 53 and required undue experimentation, among other things, in order to practice the full scope of the claimed inventions.

91. The UWA Patents are further invalid under the indefiniteness requirement of 35 U.S.C. § 112.

CLAIM III
(Infringement of the '361 Patent)

92. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

93. Claim 1 of the '361 Patent claims:

> 1. An antisense oligomer which causes skipping of the 53rd exon in the human dystrophin gene, consisting of the nucleotide sequence of SEQ ID NO: 57, wherein the antisense oligomer is an oligonucleotide in which the sugar moiety and/or the phosphate-binding region of at least one nucleotide constituting the oligonucleotide is modified, or a morpholino oligomer.

94. "Golodirsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Highlights of Prescribing Information (Dec. 12, 2019) § 11. "Golodirsen contains 25 linked subunits." *Id.*

95. "Golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 12.1.

96. "The sequence of bases from the 5' end to 3' end [of golodirsen] is GTTGCCTCCGGTTCTGAAGGTGTTC." *Id.*

97. VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the ’361 Patent.

98. On information and belief, Sarepta has infringed the ’361 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the ’ 361 Patent in violation of 35 U.S.C. § 271(a).

99. VYONDYS 53 is indicated “for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.” Highlights of Prescribing Information (Dec. 12, 2019) § 1. As such, VYONDYS 53 is not suitable for substantial non-infringing uses.

100. On information and belief, Sarepta has contributorily infringed the ’ 361 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the ’ 361 Patent in violation of 35 U.S.C. § 271(c).

101. Sarepta’s labels for VYONDYS 53 encourage physicians and patients to use VYONDYS 53 to treat “Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.” Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1.

102. On information and belief, Sarepta has induced infringement of the ’ 361 Patent by encouraging others to use VYONDYS 53 in the United States before the expiration of the ’ 361 Patent in violation of 35 U.S.C. § 271(b).

103. On information and belief, Sarepta’s infringement of the ’361 Patent has been willful. Sarepta had knowledge of the ’361 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the ’361 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

104. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285

CLAIM IV
(Infringement of the '092 Patent)

105. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

106. Claim 1 of the '092 Patent claims:

> 1. A phosphorodiamidate morpholino oligomer (PMO) antisense oligomer that causes skipping of the 53rd exon in a human dystrophin pre-mRNA, consisting of a 25-mer oligomer that is 100% complementary to the 36th to the 60th nucleotides from the 5' end of the 53rd exon in said human dystrophin pre-mRNA, wherein the 53rd exon in said human dystrophin pre-mRNA consists of a nucleotide sequence corresponding to SEQ ID NO: 1, and wherein said PMO antisense oligomer hybridizes to said pre-mRNA with Watson-Crick base pairing under physiological conditions.

107. "Golodirsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Highlights of Prescribing Information (Dec. 12, 2019) § 11. "Golodirsen contains 25 linked subunits." *Id.*

108. "The sequence of bases from the 5' end to 3' end [of golodirsen] is GTTGCCTCCGGTTCTGAAGGTGTTC." *Id.*

109. The sequence 5'–GTTGCCTCCGGTTCTGAAGGTGTTC–3' is 100% complementary to the 36th to the 60th nucleotides from the 5' end of the 53rd exon in human dystrophin pre-mRNA that consists of a nucleotide sequence corresponding to SEQ ID NO: 1:

Positions 36 to 60 form the 5' end of SEQ ID No. 1 (shown 3' to 5')																										
3'	**C**	**A**	**A**	**C**	**G**	**G**	**A**	**G**	**G**	**C**	**C**	**A**	**A**	**G**	**A**	**C**	**T**	**T**	**C**	**C**	**A**	**C**	**A**	**A**	**G**	**5'**
5'	**G**	**T**	**T**	**G**	**C**	**C**	**T**	**C**	**C**	**G**	**G**	**T**	**T**	**C**	**T**	**G**	**A**	**A**	**G**	**G**	**T**	**G**	**T**	**T**	**C**	**3'**
Golodirsen (shown 5' to 3')																										

110. "Golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 12.1.

111. VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '092 Patent.

112. On information and belief, Sarepta has infringed the '092 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the '092 Patent in violation of 35 U.S.C. § 271(a).

113. VYONDYS 53 is indicated "for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 1. As such, VYONDYS 53 is not suitable for substantial non-infringing uses.

114. On information and belief, Sarepta has contributorily infringed the '092 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the '092 Patent in violation of 35 U.S.C. § 271(c).

115. Sarepta's labels for VYONDYS 53 encourage physicians and patients to use VYONDYS 53 to treat "Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1.

116. On information and belief, Sarepta has induced infringement of the '092 Patent by encouraging others to use VYONDYS 53 in the United States before the expiration of the '092 Patent in violation of 35 U.S.C. § 271(b).

117. On information and belief, Sarepta's infringement of the '092 Patent has been willful. Sarepta had knowledge of the '092 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the '092 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

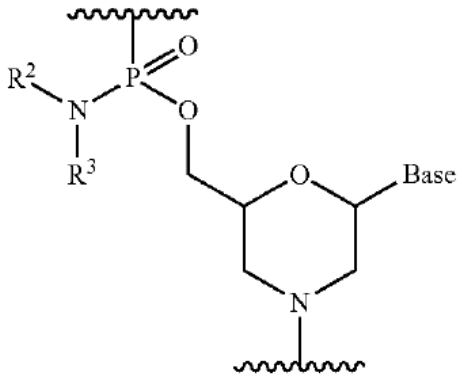
118. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

CLAIM V
(Infringement of the '461 Patent)

119. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

120. Claim 1 of the '461 Patent claims:

> 1. A phosphorodiamidate morpholino oligomer (PMO) antisense oligomer that causes skipping of the 53rd exon in a human dystrophin pre-mRNA, consisting of a 25-mer oligomer that is 100% complementary to the target sequence 5'-GAACACCUUCAGAACCGGAGGCAAC-3' (SEQ ID NO: 124) of said human dystrophin pre-mRNA, wherein said PMO antisense oligomer hybridizes to said target sequence with Watson-Crick base pairing under physiological conditions, wherein each phosphorodiamidate morpholino monomer of said PMO antisense oligomer has the formula:

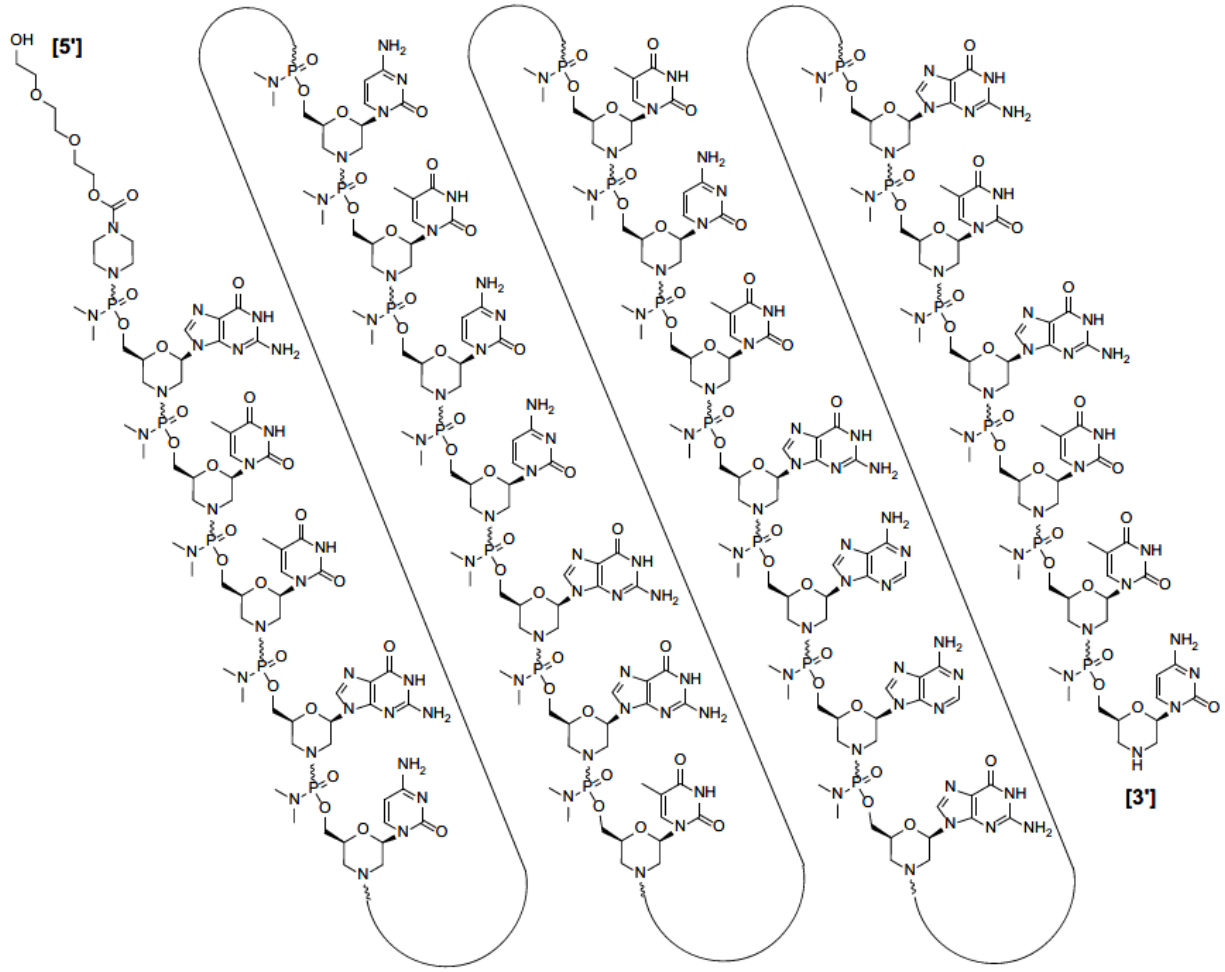


> wherein each of R^2 and R^3 represents a methyl; and wherein Base is a nucleobase selected from the group consisting of uracil, cytosine, thymine, adenine, and guanine.

121. The sequence 5'–GTTGCCTCCGGTTCTGAAGGTGTTC–3' is 100% complementary to the target sequence 5'-GAACACCUUCAGAACCGGAGGCAAC-3' (SEQ ID NO: 124):

SEQ ID No. 124 (shown 3' to 5')																									
3'	**C**	**A**	**A**	**C**	**G**	**G**	**A**	**G**	**G**	**C**	**C**	**A**	**A**	**G**	**A**	**C**	**U**	**U**	**C**	**C**	**A**	**C**	**A**	**A**	**G**	**5'**
5'	**G**	**T**	**T**	**G**	**C**	**C**	**T**	**C**	**C**	**G**	**G**	**T**	**T**	**C**	**T**	**G**	**A**	**A**	**G**	**G**	**T**	**G**	**T**	**T**	**C**	**3'**
Golodirsen (shown 5' to 3')																									

122. The structure of golodirsen is:



Highlights of Prescribing Information (Dec. 12, 2019) § 11. As shown above, each monomer of golodirsen has methyl groups at the locations corresponding to R^2 and R^3 and a Base that is cytosine, thymine, adenine, or guanine.

123. As discussed above, VYONDYS 53 meets the remaining elements of claim 1 of the '461 Patent. VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '461 Patent.

124. On information and belief, Sarepta has infringed the ’461 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the ’461 Patent in violation of 35 U.S.C. § 271(a).

125. On information and belief, Sarepta has contributorily infringed the ’092 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the ’461 Patent in violation of 35 U.S.C. § 271(c).

126. On information and belief, Sarepta has induced infringement of the ’461 Patent by encouraging others to use VYONDYS 53 in the United States before the expiration of the ’461 Patent in violation of 35 U.S.C. § 271(b).

127. On information and belief, Sarepta’s infringement of the ’461 Patent has been willful. Sarepta had knowledge of the ’461 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the ’461 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

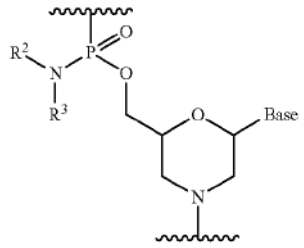
128. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

CLAIM VI
(Infringement of the ’106 Patent)

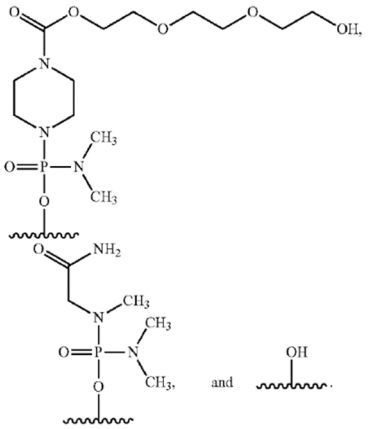
129. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

130. Claim 1 of the ’106 Patent claims:

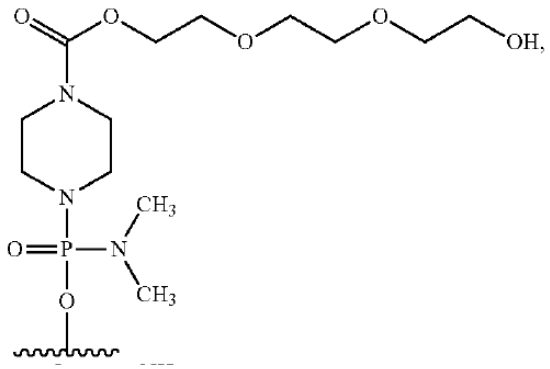
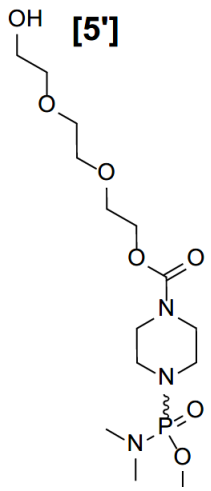
> 1. A phosphorodiamidate morpholino oligomer (PMO) consisting of a 25-mer antisense oligomer that is 100% complementary, according to Watson-Crick base pairing, to the 36th to the 60th nucleotides from the 5’ end of the 53rd exon in a human dystrophin pre-mRNA, wherein the 53rd exon in said human dystrophin pre-mRNA consists of a nucleotide sequence corresponding to SEQ ID NO: 1, wherein each phosphorodiamidate morpholino monomer of said PMO has the formula:



wherein each of R^2 and R^3 represents a methyl; and wherein Base is a nucleobase selected from the group consisting of cytosine, thymine, adenine, and guanine; and wherein the 5' end of said PMO has a formula selected from the group consisting of:



131. The 5’ end of golodirsen has at least the claimed formula shown below:

 **Claim 1**	 **Golodirsen**

132. As discussed above, VYONDYS 53 meets the remaining elements of claim 1 of the '106 Patent. VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '106 Patent.

133. On information and belief, Sarepta has infringed the '106 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the '106 Patent in violation of 35 U.S.C. § 271(a).

134. On information and belief, Sarepta has contributorily infringed the '092 Patent by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States of VYONDYS 53 before the expiration of the '106 Patent in violation of 35 U.S.C. § 271(c).

135. On information and belief, Sarepta has induced infringement of the '106 Patent by encouraging others to use VYONDYS 53 in the United States before the expiration of the '106 Patent in violation of 35 U.S.C. § 271(b).

136. On information and belief, Sarepta's infringement of the '106 Patent has been willful. Sarepta had knowledge of the '106 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the '106 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

137. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

CLAIM VII
(Infringement of the '741 Patent)

138. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

139. Claim 1 of the '741 Patent claims:

> 1. A method comprising administering to a patient with DMD an antisense phosphorodiamidate morpholino oligomer (PMO) consisting of a 25-mer oligomer

> that is 100% complementary to the 36th to the 60th nucleotides from the 5' end of the 53rd exon in a human dystrophin pre-mRNA, wherein the 53rd exon in said human dystrophin pre-mRNA consists of a nucleotide sequence corresponding to SEQ ID NO: 1, wherein said PMO hybridizes to said human dystrophin pre-mRNA with Watson-Crick base pairing, and wherein skipping of the 53rd exon is induced in said patient.

140. Sarepta's label for VYONDYS 53 encourage physicians to administer VYONDYS 53 to treat "Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1.

141. This administration of VYONDYS 53 "result[s] in exclusion of this exon [exon 53 of dystrophin pre-mRNA] during mRNA processing in patients." Highlights of Prescribing Information (Dec. 12, 2019) § 12.1; Highlights of Prescribing Information (Feb. 11, 2021) § 12.1.

142. As discussed above, VYONDYS 53 meets the remaining elements of claim 1 of the '741 Patent. This use of VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '741 Patent.

143. On information and belief, Sarepta has induced infringement of the '741 Patent by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of VYONDYS 53 for the purpose of administration to DMD patients and encouraging others to use the claimed methods in the United States before the expiration of the '741 Patent in violation of 35 U.S.C. § 271(b).

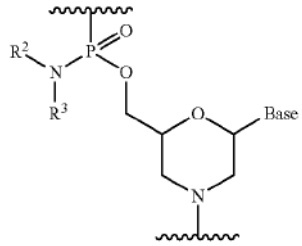
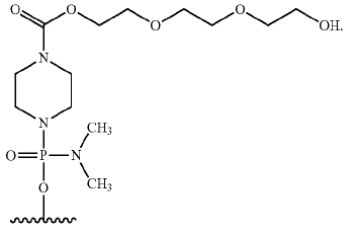
144. On information and belief, Sarepta's infringement of the '741 Patent has been willful. Sarepta had knowledge of the '741 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the '741 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

145. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

CLAIM VIII
(Infringement of the '217 Patent)

146. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

147. Claim 1 of the '217 Patent claims:

> 1. A method of treating a DMD patient comprising intravenously administering to said patient an oligomer comprising:
> a) a phosphorodiamidate morpholino oligomer (PMO) that is 100% complementary to the 36th to the 60th nucleotides from the 5' end of the 53rd exon in a human dystrophin pre-mRNA, wherein the 53rd exon in said human dystrophin pre-mRNA consists of a nucleotide sequence corresponding to SEQ ID NO: 1, wherein said PMO hybridizes to said human dystrophin pre-mRNA with Watson-Crick base pairing, wherein the phosphorodiamidate morpholino monomers of said PMO have the formula:
>
> 
>
>
> wherein each of R^2 and R^3 represents a methyl; and wherein Base is a nucleobase selected from the group consisting of cytosine, thymine, adenine, and guanine; and
> b) a group at the 5' end of said PMO with the formula:
>
> 
>

148. Sarepta's label for VYONDYS 53 encourage physicians to administer VYONDYS 53 to treat "Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of

the DMD gene that is amenable to exon 53 skipping." Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1.

149. Sarepta's label for VYONDYS 53 specifically instructs physicians that "VYONDYS 53 is administered via intravenous infusion." Highlights of Prescribing Information (Dec. 12, 2019) § 2.4; Highlights of Prescribing Information (Feb. 11, 2021) § 2.4.

150. As discussed above, VYONDYS meets the remaining elements of claim 1 of the '217 Patent. This use of VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '217 Patent.

151. On information and belief, Sarepta has induced infringement of the '217 Patent by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of VYONDYS 53 for the purpose of administration to DMD patients and encouraging others to use the claimed methods in the United States before the expiration of the '217 Patent in violation of 35 U.S.C. § 271(b).

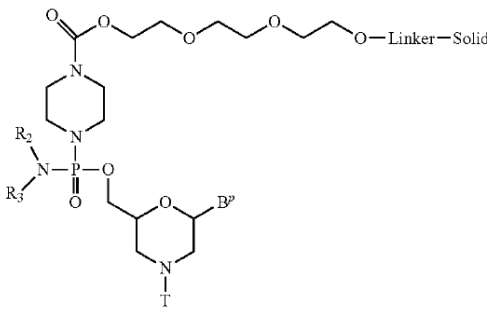
152. On information and belief, Sarepta's infringement of the '217 Patent has been willful. Sarepta had knowledge of the '217 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the '217 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

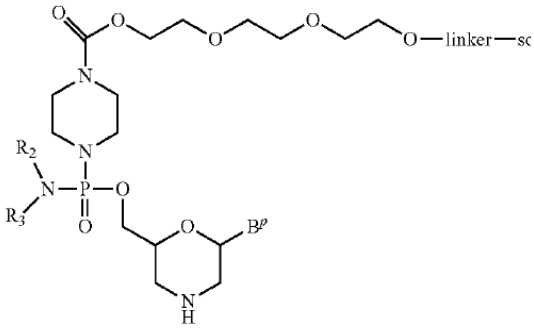
153. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

CLAIM IX
(Infringement of the '322 Patent)

154. Nippon Shinyaku realleges and incorporates by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

155. On information and belief, Sarepta's manufacturing process for VYONDYS 53 includes (i) reacting the compound shown below left with an acid to form the compound shown below right; and then (ii) reacting the compound shown below right with a morpholino monomer in the presence of a base and a solvent.

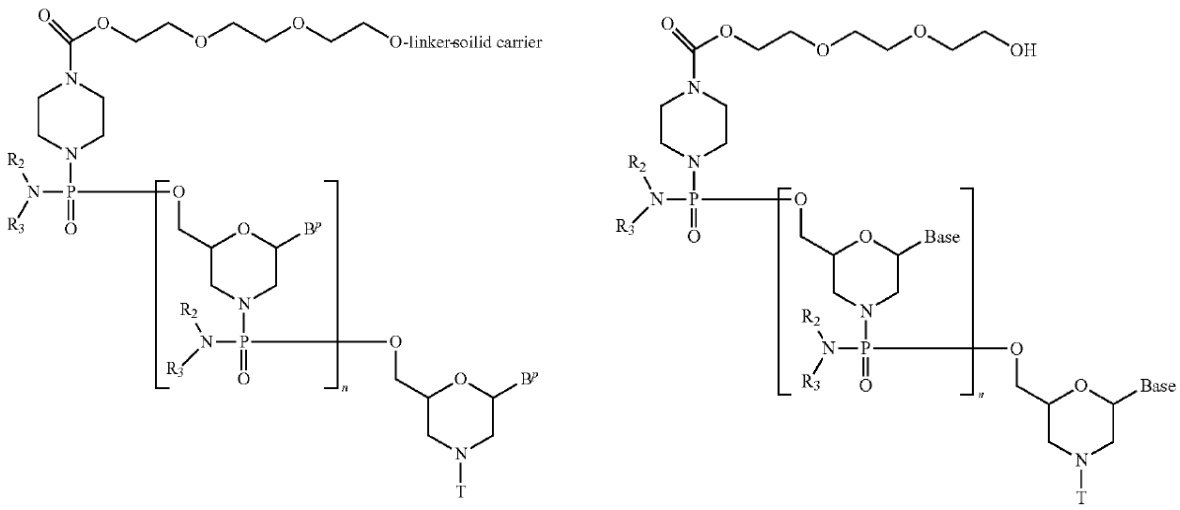




wherein T represents trityl, monomethoxytrityl, or
thoxytrityl; wherein each of R^2 and R^3 repres
methyl; and wherein B^P is a protected Base,

156. On information and belief, Sarepta's manufacturing process for VYONDYS 53 includes iteratively reacting the resultant compound first with an acid and then second with a morpholino monomer in the presence of a base and a solvent to add phosphorodiamidate morpholino monomers to the compound.

157. On information and belief, this iterative process results in the compound shown below left, which Sarepta reacts with a deprotecting agent to form the compound shown below right:



158. On information and belief, Sarepta's manufacturing process for VYONDYS 53 includes reacting the compound shown above right with an acid to form a phosphorodiamidate morpholino oligomer.

159. On information and belief, Sarepta's manufacturing process for VYONDYS 53 satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '322 Patent.

160. On information and belief, Sarepta has infringed the '322 Patent by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of VYONDYS 53 before the expiration of the '322 Patent in violation of 35 U.S.C. § 271(a) and (g).

161. As discussed above, VYONDYS meets the remaining elements of claim 1 of the '322 Patent. This use of VYONDYS 53 thus satisfies each element and infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '322 Patent.

162. On information and belief, Sarepta has induced and/or contributed to infringement of the '322 Patent by engaging in the commercial manufacture, use, offer to sell, sale, or importation into the United States of VYONDYS 53 for the purpose of administration to DMD

patients and encouraging others to use the claimed methods in the United States before the expiration of the '322 Patent in violation of 35 U.S.C. § 271(b).

163. On information and belief, Sarepta's infringement of the '322 Patent has been willful. Sarepta had knowledge of the '322 Patent. Despite this knowledge, Sarepta continues to knowingly, willfully, deliberately, maliciously, and in bad faith infringe the '322 Patent, and, in doing so, knew or should have known that its conduct amounted to infringement.

164. This case is exceptional, and Nippon Shinyaku is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Nippon Shinyaku prays for judgment against Defendant Sarepta, respectfully requests the following relief:

1. A judgment that Sarepta has breached the MCA, including by having breached its obligations under Section 10;

2. A declaration of Sarepta's obligations under Section 10 of the MCA;

3. An order of specific performance of Sarepta's obligations under Section 10 of the MCA, including preliminary and permanent injunctions enjoining Sarepta, and its officers, agents, servants, and employees, and those persons acting in active concert or participation with all or any of them, from breaching its obligations under the MCA, and requiring Sarepta and said individuals to seek withdrawal and dismissal at the PTAB of the IPR Petitions;

4. An award of all legal fees and costs, including attorneys' fees, that Nippon Shinyaku incurs to prepare for and conduct its breach of contract action against Sarepta, as well as all legal fees and costs, including attorneys' fees, that Nippon Shinyaku incurs to oppose Sarepta's challenges before the PTAB;

5. A judgment that the UWA Patents are invalid;

6. A judgment that Sarepta has been and will continue infringing each of the NS Patents;

7. A judgment that Sarepta's infringement was willful and trebling any damages found or assessed;

8. To the extent that Sarepta has or will commercially manufacture, use, offer to sell, or sell VYONDYS 53 within the United States, or import VYONDYS 53 into the United States, prior to the expiration of the NS Patents, including any extensions, a judgment awarding Nippon Shinyaku monetary relief together with interest;

9. A judgment that this is an exceptional case and that Nippon Shinyaku be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

10. Costs and expenses in this action; and

11. Such other and further relief as the Court deems just and appropriate.

DEMAND FOR A JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(c), Nippon Shinyaku demands a jury trial solely regarding claims II-IX of the instant Amended Complaint.

Dated: January 14, 2022

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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Attorneys for Plaintiff Nippon Shinyaku Co., Ltd.

Exhibit II

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	)	C.A. No. 21-1015 (LPS) **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC., Defendant and Counter-Plaintiff, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff and Counter-Defendants.	)	

DEFENDANT SAREPTA THERAPEUTICS, INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF NIPPON SHINYAKU CO., LTD.'S SECOND AMENDED COMPLAINT

Defendant Sarepta Therapeutics, Inc. ("Sarepta"), by and through its undersigned counsel, hereby submits its Answer and Defenses to Plaintiff Nippon Shinyaku Co., Ltd.'s ("Nippon Shinyaku") Second Amended Complaint for Breach of Contract, Declaratory Judgment of Patent Invalidity, and Patent Infringement ("SAC") (D.I. 86), filed January 14, 2022. In addition, Sarepta asserts the counterclaims below against Nippon Shinyaku and its wholly owned U.S. subsidiary, NS Pharma, Inc. ("NS Pharma").

ANSWER

Nature of the Action[1]

1. Sarepta admits that the SAC purports to assert a claim for breach of contract. Sarepta admits that it entered into a Mutual Confidentiality Agreement ("MCA") with Nippon Shinyaku. Sarepta admits that it filed seven petitions for *inter partes* review (collectively, the "IPR Petitions") with the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO"), challenging the patentability of all claims of Nippon Shinyaku's U.S. Patent Nos. 9,708,361 ("the '361 patent"); 10,385,092 ("the '092 patent); 10,407,461 ("the '461 patent"); 10,487,106 ("the '106 patent"); 10,647,741 ("the '741 patent"); 10,662,217 ("the '217 patent"); and 10,683,322 ("the '322 patent) (collectively, "the NS Patents").[2] Sarepta denies any remaining allegations in Paragraph 1.

2. Sarepta admits that the SAC purports to assert claims for declaratory judgment of invalidity of the University of Western Australia's ("UWA") U.S. Patent Nos. 9,994,851 ("the '851 patent"); 10,227,590 ("the '590 patent"); and 10,266,827 ("the '827 patent") (collectively, "the UWA Patents"). Sarepta admits that it has exclusive rights to the UWA Patents for the treatment of muscular dystrophies and the right to enforce the UWA Patents. Sarepta denies any remaining allegations in Paragraph 2.

[1] For convenience and clarity, Sarepta's Answer uses the same headings as the SAC. Sarepta does not admit any allegations contained in the SAC's headings.

[2] *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134 (U.S. Patent No. 9,708,361); IPR2021-01135 (U.S. Patent No. 10,385,092); IPR2021-01136 (U.S. Patent No. 10,407,461); IPR2021-01137 (U.S. Patent No. 10,487,106); IPR2021-01138 (U.S. Patent No. 10,647,741); IPR2021-01139 (U.S. Patent No. 10,662,217); IPR2021-01140 (U.S. Patent No. 10,683,322).

3. Sarepta admits that the SAC further purports to assert claims for infringement of the NS Patents. Sarepta admits that it developed golodirsen (SRP-4053) and has marketed it as Vyondys 53® in the United States. Sarepta admits that Vyondys 53® is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer subclass that induces skipping of exon 53 of the human dystrophin gene to treat Duchenne Muscular Dystrophy ("DMD"). Sarepta denies any remaining allegations in Paragraph 3.

Parties

4. Upon information and belief, Sarepta admits the allegations in Paragraph 4.

5. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 5 and therefore denies them.

6. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 6 and therefore denies them.

7. Sarepta admits the allegations in Paragraph 7.

Jurisdiction and Venue

8. Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the SAC purports to assert a breach of contract claim under Delaware law. Sarepta denies any remaining allegations in Paragraph 8.

9. Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the SAC purports to assert a claim for declaratory judgment of invalidity of the UWA Patents under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Sarepta denies any remaining allegations in Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta denies that the Court has subject matter jurisdiction over Claim I (Breach of Contract) and Claim II of the SAC (Declaratory Judgment of Invalidity of the UWA Patents). For purposes of this action only, Sarepta does not contest that the Court has subject matter jurisdiction over Claims III-IX of the SAC. Sarepta denies any remaining allegations in Paragraph 10.

11. Sarepta admits that it competes with Nippon Shinyaku in developing and commercializing exon 53 skipping therapies for the treatment of DMD in patients amenable to exon 53 skipping in the United States. Upon information and belief, Sarepta admits that Sarepta and Nippon Shinyaku are the only companies with approval from the U.S. Food and Drug Administration ("FDA") to market oligonucleotide therapies for the treatment of DMD in patients amenable to exon 53 skipping in the United States. Sarepta admits that its Vyondys 53® (golodirsen) product was approved by the FDA. Upon information and belief, Sarepta admits that Nippon Shinyaku's Viltepso (viltolarsen) product was subsequently approved by the FDA. Sarepta denies any remaining allegations in Paragraph 11.

12. Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the UWA was granted U.S. Patent Nos. 8,455,636 ("the '636 patent") and 9,024,007 ("the '007 patent"), entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." Sarepta admits that the '636 and '007 patents were issued by the USPTO on June 4, 2013 and May 5, 2015, respectively. Sarepta admits that the claims of the '636 and '007 patents cover Sarepta's Vyondys 53® (golodirsen) product. Sarepta denies any remaining allegations in Paragraph 12.

13. Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the UWA Patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Vyondys 53®. Sarepta admits that the Orange Book lists a patent expiry date of June 28, 2025 for the UWA Patents. Sarepta admits that it has submitted applications for patent term extension for the UWA Patents. Sarepta denies any remaining allegations in Paragraph 13.

14. Sarepta denies the allegations in Paragraph 14.

15. Sarepta admits that Matthew Gall of Sarepta attended a meeting with Masaya Toda of Nippon Shinyaku on or about January 13, 2020 to discuss a potential business relationship between Sarepta and Nippon Shinyaku. Sarepta is without sufficient knowledge or information to form a belief as to what Nippon Shinyaku understood the parties to have discussed, and therefore denies the same. Sarepta denies any remaining allegations in Paragraph 15.

16. Sarepta admits that Chris Verni, Sarepta's Chief IP counsel, spoke with Nippon Shinyaku's outside counsel on or about January 28, 2020 while attending a conference for the Association of Corporate Patent Counsel. Sarepta denies any remaining allegations in Paragraph 16.

17. Sarepta admits that, after June 1, 2021, it had not granted Nippon Shinyaku a license or covenant not to sue for the UWA Patents, and Nippon Shinyaku had not granted Sarepta a license or covenant not to sue for the NS Patents. Sarepta denies any remaining allegations in Paragraph 17.

18. Sarepta admits that on or about July 6, 2021, Joe Zenkus of Sarepta sent an email to Masaya Toda of Nippon Shinyaku regarding Sarepta's filing of the IPR petitions challenging the patentability of the NS Patents. Sarepta admits that Paragraph 18 quotes a portion of Nippon

Shinyaku's Exhibit D.I. 39-4 (with alteration to original). Sarepta denies any remaining allegations in Paragraph 18.

19. Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 19 quotes (with emphasis added) a portion of Nippon Shinyaku's Exhibit D.I. 39-4. Sarepta is without sufficient knowledge or information to form a belief as to Nippon Shinyaku's beliefs, and therefore denies the same. Sarepta denies any remaining allegations in Paragraph 19.

20. Sarepta admits that on or about September 8, 2021, Nippon Shinyaku sent Sarepta a proposed covenant not to sue Nippon Shinyaku for infringement of the UWA Patents, which Nippon Shinyaku requested that Sarepta execute and return to Nippon Shinyaku no later than the close of business on September 10, 2021. Sarepta admits that it did not execute the proposed covenant not to sue. Sarepta denies any remaining allegations in Paragraph 20.

21. Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Nippon Shinyaku's SAC purports to assert claims for patent infringement of the NS Patents under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.* Sarepta denies any remaining allegations in Paragraph 21.

22. Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Nippon Shinyaku's SAC alleges that the amount in controversy exceeds $75,000, exclusive of interest and costs. Sarepta denies any remaining allegations in Paragraph 22.

23. Sarepta admits that it markets, offers to sell, and/or sells Vyondys 53® in the United States, including in Delaware. Sarepta denies any remaining allegations in Paragraph 23.

24. Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 24 alleges that this Court has subject matter jurisdiction over Nippon Shinyaku's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a). For purposes of this action only, Sarepta does not contest that the Court has subject matter jurisdiction over those patent infringement claims. Sarepta denies any remaining allegations in Paragraph 24.

25. Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that it is a Delaware corporation. Sarepta does not contest that this Court has personal jurisdiction over it for purposes of this action only. Sarepta denies any remaining allegations in Paragraph 25.

26. Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that it is a Delaware corporation. Sarepta does not contest that venue is proper in the District of Delaware for purposes of this action only. Sarepta denies any remaining allegations in Paragraph 26.

Duchenne Muscular Dystrophy

27. Sarepta admits that DMD is a rare genetic disorder characterized by progressive muscle deterioration and weakness, which primarily affects boys but in rare cases can affect girls. Sarepta admits that DMD often occurs in people without a known family history of the condition. Sarepta admits that DMD occurs in about one out of every 3,600 male infants worldwide and is the most common type of muscular dystrophy. Sarepta admits that the first symptoms usually present between three- and five-years old and worsen over time. Sarepta admits that patients with DMD progressively lose the ability to perform everyday activities and often require a wheelchair and assistance by their early teens. Sarepta admits that as DMD progresses, life-threatening heart

and respiratory conditions can occur, and patients, although disease severity and life expectancy vary, typically die of the disease in their 20s or 30s. Sarepta denies any remaining allegations in Paragraph 27.

28. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 28 and therefore denies them.

29. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 29 and therefore denies them.

30. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 30 and therefore denies them.

31. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 31 and therefore denies them.

32. Sarepta admits that in Becker Muscular Dystrophy (BMD), in-frame mutations in the dystrophin gene result in truncated but functional dystrophin. Sarepta admits that BMD patients typically experience milder symptoms than DMD patients, ranging from borderline DMD to no symptoms at all. Sarepta denies any remaining allegations in Paragraph 32.

33. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 33 and therefore denies them.

Exon-Skipping Antisense Oligomers as a Therapeutic Option

34. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 34 and therefore denies them.

35. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 35 and therefore denies them.

Nippon Shinyaku's Development of Exon 53 Skipping Oligomers

36. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 36 and therefore denies them.

37. Upon information and belief, Sarepta admits that Nippon Shinyaku purports to have filed Japanese Patent Application No. 2010-196032 with the National Center of Neurology and Psychiatry ("NCNP") on September 1, 2010. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in Paragraph 37 and therefore denies them.

38. Upon information and belief, Sarepta admits that Nippon Shinyaku obtained approval in Japan and the United States for Viltepso. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in Paragraph 38 and therefore denies them.

The NS Patents-In-Suit

39. Sarepta admits that the '361 patent is entitled "Antisense Nucleic Acids" and states that it was issued on July 18, 2017. Sarepta admits that the '361 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku's Exhibit D.I. 2-2 purports to be a copy of the '361 patent. Sarepta denies that the '361 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 39.

40. Sarepta admits that the '092 patent is entitled "Antisense Nucleic Acids" and states that it was issued on August 20, 2019. Sarepta admits that the '092 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku's Exhibit D.I. 2-3 purports to

be a copy of the ’092 patent. Sarepta denies that the ’092 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 40.

41. Sarepta admits that the ’461 patent is entitled “Antisense Nucleic Acids” and states that it was issued on September 10, 2019. Sarepta admits that the ’461 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin’ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku’s Exhibit D.I. 2-4 purports to be a copy of the ’461 patent. Sarepta denies that the ’461 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 41.

42. Sarepta admits that the ’106 patent is entitled “Antisense Nucleic Acids” and states that it was issued on November 26, 2019. Sarepta admits that the ’106 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin’ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku’s Exhibit D.I. 2-5 purports to be a copy of the ’106 patent. Sarepta denies that the ’106 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 42.

43. Sarepta admits that the ’741 patent is entitled “Antisense Nucleic Acids” and states that it was issued on May 12, 2020. Sarepta admits that the ’741 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin’ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku’s Exhibit D.I. 2-6 purports to be a copy of the ’741 patent. Sarepta denies that the ’741 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 43.

44. Sarepta admits that the ’217 patent is entitled “Antisense Nucleic Acids” and states that it was issued on May 26, 2020. Sarepta admits that the ’217 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin’ichi Takeda, and

Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku's Exhibit D.I. 2-7 purports to be a copy of the '217 patent. Sarepta denies that the '217 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 44.

45. Sarepta admits that the '322 patent is entitled "Antisense Nucleic Acids" and states that it was issued on June 16, 2020. Sarepta admits that the '322 patent lists, on its face, Nippon Shinyaku and NCNP as assignees, and Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata as inventors. Sarepta admits that Nippon Shinyaku's Exhibit D.I. 2-8 purports to be a copy of the '322 patent. Sarepta denies that the '322 patent is valid or enforceable. Sarepta denies any remaining allegations in Paragraph 45.

46. Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Nippon Shinyaku's Exhibit D.I. 39-5 purports to be a license agreement between Nippon Shinyaku and NCNP. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in Paragraph 46 and therefore denies them.

47. Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 47 and therefore denies them.

48. Paragraph 48 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in Paragraph 48 and therefore denies them.

The UWA Patents

49. Sarepta admits that, on June 12, 2018, the '851 patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to UWA as

assignee with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. Sarepta admits that it has exclusive rights to the '851 patent for the treatment of muscular dystrophies and the right to enforce the '851 patent. Sarepta denies any remaining allegations in Paragraph 49.

50. Sarepta admits that, on March 12, 2019, the '590 patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to UWA as assignee with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. Sarepta admits that it has exclusive rights to the '590 patent for the treatment of muscular dystrophies and the right to enforce the '590 patent. Sarepta denies any remaining allegations in Paragraph 50.

51. Sarepta admits that, on April 23, 2019, the '827 patent entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" issued to UWA as assignee with named inventors Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. Sarepta admits that it has exclusive rights to the '827 patent for the treatment of muscular dystrophies and the right to enforce the '827 patent. Sarepta denies any remaining allegations in Paragraph 51.

Sarepta's Infringing Product

52. Paragraph 52 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Vyondys 53® is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer subclass that contains 25 linked subunits and is designed to bind to exon 53 of human dystrophin pre-RNA. Sarepta denies any remaining allegations in Paragraph 52.

53. Sarepta admits that Vyondys 53® is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing. Sarepta denies any remaining allegations in Paragraph 53.

54. Paragraph 54 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Vyondys 53® is administered to patients and is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with a genetic mutation that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 54.

55. Sarepta denies the allegations in Paragraph 55.

56. Sarepta admits that it sponsored clinical trials in the United States for Vyondys 53® (golodirsen). Sarepta denies any remaining allegations in Paragraph 56.

57. Sarepta admits that the FDA issued a press release on December 12, 2019, stating that it granted accelerated approval of Vyondys® 53 (golodirsen) to treat DMD patients who have a confirmed mutation of the dystrophin gene amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 57.

58. Sarepta admits that on December 12, 2019, it issued a press release containing a statement partially quoted in Paragraph 58. Sarepta denies any remaining allegations in Paragraph 58.

59. Paragraph 59 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that, following FDA approval, it has marketed, offered to sell, and/or sold Vyondys 53® in the United States for the treatment of DMD patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta admits that its Form 10-K Annual Report for 2020 refers to Vyondys 53® as a commercial

product and states that Vyondys 53® was sold in 2020 and 2019. Sarepta denies any remaining allegations in Paragraph 59.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that it markets, offers to sell, and/or sells Vyondys 53® in the United States for the treatment of DMD patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 60.

Sarepta's Breach of the MCA

61. Sarepta admits the allegations in Paragraph 61.

62. Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 62 quotes a portion of Section 6.1 of the MCA. Sarepta denies any remaining allegations in Paragraph 62.

63. Paragraph 63 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 63 quotes a portion of Section 10 of the MCA. Sarepta denies any remaining allegations in Paragraph 63.

64. Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 64 quotes from the MCA's definition of "Potential Actions" in Section 1. Sarepta denies any remaining allegations in Paragraph 64.

65. Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 65 quotes from the MCA's definitions of "Covenant Term" and "Term" in Section 1. Sarepta denies any remaining allegations in Paragraph 65.

66. Sarepta admits that it filed the IPR Petitions with the PTAB on June 21, 2021, challenging the patentability of all claims of the NS Patents. Sarepta denies any remaining allegations in Paragraph 66.

CLAIM I
(Breach of Contract)

67. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

68. Paragraph 68 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta denies that the MCA is valid or enforceable under Nippon Shinyaku's legally erroneous contract interpretation. Sarepta denies any remaining allegations in Paragraph 68.

69. Sarepta admits that Paragraph 69 quotes from a portion of one sentence in Section 10 of the MCA. Sarepta denies any remaining allegations in Paragraph 69.

70. Sarepta admits that Paragraph 70 quotes the MCA's definition of "Potential Actions" in Section 1. Sarepta denies any remaining allegations in Paragraph 70.

71. Sarepta admits that it filed the IPR Petitions with the PTAB on June 21, 2021, challenging the patentability of all claims of the NS Patents. Sarepta denies any remaining allegations in Paragraph 71.

72. Sarepta denies the allegations in Paragraph 72.

73. Sarepta denies the allegations in Paragraph 73.

74. Sarepta denies the allegations in Paragraph 74.

75. Sarepta denies the allegations in Paragraph 75.

CLAIM II
(Declaratory Judgment of Invalidity of the UWA Patents)

76. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

77. Sarepta admits that it competes with Nippon Shinyaku in developing and commercializing exon 53 skipping therapies for the treatment of DMD in patients amenable to exon 53 skipping in the United States. Upon information and belief, Sarepta admits that Sarepta and Nippon Shinyaku are the only companies with approval from the FDA to market oligonucleotide therapies for the treatment of DMD in patients amenable to exon 53 skipping in the United States. Sarepta admits that its Vyondys 53® (golodirsen) product was approved by the FDA. Upon information and belief, Sarepta admits that Nippon Shinyaku's Viltepso (viltolarsen) product was subsequently approved by the FDA. Sarepta denies any remaining allegations in Paragraph 77.

78. Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that UWA was granted the '636 patent and the '007 patent, each entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." Sarepta admits that the '636 and '007 patents were issued by the USPTO on June 4, 2013 and May 5, 2015, respectively. Sarepta admits that the claims of the '636 and '007 patents cover Sarepta's Vyondys 53® (golodirsen) product. Sarepta denies any remaining allegations in Paragraph 78.

79. Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the UWA Patents are listed in the FDA Orange Book for Vyondys 53®. Sarepta admits that the Orange Book lists a patent expiry date of June 28, 2025 for the UWA Patents. Sarepta admits that it has submitted applications for patent term extension for the UWA Patents. Sarepta denies any remaining allegations in Paragraph 79.

80. Sarepta denies the allegations in Paragraph 80.

81. Sarepta admits that Matthew Gall of Sarepta attended a meeting with Masaya Toda of Nippon Shinyaku on or about January 13, 2020 to discuss a potential business relationship between Sarepta and Nippon Shinyaku. Sarepta is without sufficient knowledge or information to form a belief as to what Nippon Shinyaku understood the parties to have discussed, and therefore denies the same. Sarepta denies any remaining allegations in Paragraph 81.

82. Sarepta admits that Chris Verni, Sarepta's Chief IP counsel, spoke with Nippon Shinyaku's outside counsel on or about January 28, 2020 while attending a conference for the Association of Corporate Patent Counsel. Sarepta denies any remaining allegations in Paragraph 82.

83. Sarepta admits that, after June 1, 2021, it had not granted Nippon Shinyaku a license or covenant not to sue for the UWA Patents, and Nippon Shinyaku had not granted Sarepta a license or covenant not to sue for the NS Patents. Sarepta denies any remaining allegations in Paragraph 83.

84. Sarepta admits that on or about July 6, 2021, Joe Zenkus of Sarepta sent an email to Masaya Toda of Nippon Shinyaku regarding Sarepta's filing of the IPR petitions challenging the patentability of the NS Patents. Sarepta admits that Paragraph 84 quotes a portion of Nippon Shinyaku's Exhibit D.I. 39-4. Sarepta denies any remaining allegations in Paragraph 84.

85. Paragraph 85 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 85 quotes (with emphasis added) a portion of Nippon Shinyaku's Exhibit D.I. 39-4. Sarepta is without sufficient knowledge or information to form a belief as Nippon Shinyaku's beliefs, and therefore denies the same. Sarepta denies any remaining allegations in Paragraph 85.

86. Sarepta admits that on or about September 8, 2021, Nippon Shinyaku sent Sarepta a proposed covenant not to sue Nippon Shinyaku for infringement of the UWA Patents, which Nippon Shinyaku requested that Sarepta execute and return to Nippon Shinyaku no later than the close of business on September 10, 2021. Sarepta admits that it did not execute the proposed covenant not to sue. Sarepta denies any remaining allegations in Paragraph 86.

87. Sarepta denies the allegations in Paragraph 87.

88. Sarepta denies the allegations in Paragraph 88.

89. Sarepta denies the allegations in Paragraph 89.

90. Sarepta denies the allegations in Paragraph 90.

91. Sarepta denies the allegations in Paragraph 91.

CLAIM III
(Infringement of the '361 Patent)

92. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

93. Sarepta admits that Paragraph 93 quotes claim 1 of the '361 patent.

94. Sarepta admits that Paragraph 94 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 11." Sarepta admits that golodirsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. Sarepta denies any remaining allegations in Paragraph 94.

95. Sarepta admits that Paragraph 95 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 12.1." Sarepta admits that golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with a genetic mutation that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 95.

96. Sarepta admits that Paragraph 96 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 12.1." Sarepta admits that the sequence of bases from the 5' end to 3' end of golodirsen is GTTGCCTCCGGTTCTGAAGGTGTTC. Sarepta denies any remaining allegations in Paragraph 96.

97. Sarepta denies the allegations in Paragraph 97.

98. Sarepta denies the allegations in Paragraph 98.

99. Paragraph 99 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 99 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 1." Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 99.

100. Sarepta denies the allegations in Paragraph 100.

101. Paragraph 101 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 101 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1." Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 101.

102. Sarepta denies the allegations in Paragraph 102.

103. Sarepta denies the allegations in Paragraph 103.

104. Sarepta denies the allegations in Paragraph 104.

CLAIM IV
(Infringement of the '092 Patent)

105. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

106. Sarepta admits that Paragraph 106 quotes claim 1 of the '092 patent.

107. Sarepta admits that Paragraph 107 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 11." Sarepta admits that golodirsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. Sarepta admits that golodirsen contains 25 linked subunits. Sarepta denies any remaining allegations in Paragraph 107.

108. Sarepta admits that Paragraph 108 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) §11." Sarepta admits that the sequence of bases of golodirsen from the 5' end to 3' end is GTTGCCTCCGGTTCTGAAGGTGTTC. Sarepta denies any remaining allegations in Paragraph 108.

109. Paragraph 109 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta denies the allegations in Paragraph 109.

110. Sarepta admits that Paragraph 110 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 12.1." Sarepta admits that golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with a genetic mutation that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 110.

111. Sarepta denies the allegations in Paragraph 111.

112. Sarepta denies the allegations in Paragraph 112.

113. Paragraph 113 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 113 purports to quote in part from

"Highlights of Prescribing Information (Dec. 12, 2019) § 1." Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 113.

114. Sarepta denies the allegations in Paragraph 114.

115. Paragraph 115 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 115 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1." Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 115.

116. Sarepta denies the allegations in Paragraph 116.

117. Sarepta denies the allegations in Paragraph 117.

118. Sarepta denies the allegations in Paragraph 118.

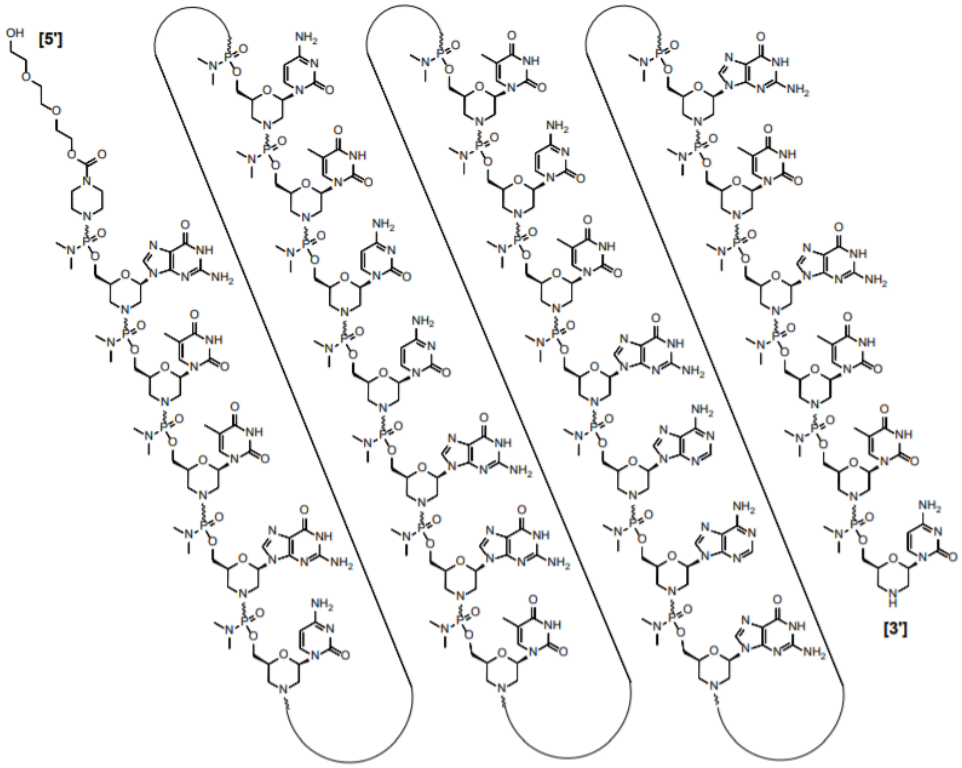
CLAIM V
(Infringement of the '461 Patent)

119. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

120. Sarepta admits that Paragraph 120 quotes claim 1 of the '461 patent.

121. Paragraph 121 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta denies the allegations in Paragraph 121.

122. Paragraph 122 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the label for Vyondys 53® indicates that the structure of golodirsen is:



Sarepta denies any remaining allegations in Paragraph 122.

123. Sarepta denies the allegations in Paragraph 123.

124. Sarepta denies the allegations in Paragraph 124.

125. Sarepta denies the allegations in Paragraph 125.

126. Sarepta denies the allegations in Paragraph 126.

127. Sarepta denies the allegations in Paragraph 127.

128. Sarepta denies the allegations in Paragraph 128.

CLAIM VI
(Infringement of the '106 Patent)

129. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

130. Sarepta admits that Paragraph 130 quotes claim 1 of the '106 patent.

131. Paragraph 131 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that the label for Vyondys 53® describes the structure of golodirsen. Sarepta denies any remaining allegations in Paragraph 131.

132. Sarepta denies the allegations in Paragraph 132.

133. Sarepta denies the allegations in Paragraph 133.

134. Sarepta denies the allegations in Paragraph 134.

135. Sarepta denies the allegations in Paragraph 135.

136. Sarepta denies the allegations in Paragraph 136.

137. Sarepta denies the allegations in Paragraph 137.

CLAIM VII
(Infringement of the '741 Patent)

138. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

139. Sarepta admits that Paragraph 139 quotes claim 1 of the '741 patent.

140. Paragraph 140 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Paragraph 140 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019) § 1; Highlights of Prescribing Information (Feb. 11, 2021) § 1." Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 140.

141. Sarepta admits that Paragraph 141 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019)" and "Highlights of Prescribing Information (Feb. 11, 2021)." Sarepta admits that golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with a genetic mutation that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 141.

142. Sarepta denies the allegations in Paragraph 142.

143. Sarepta denies the allegations in Paragraph 143.

144. Sarepta denies the allegations in Paragraph 144.

145. Sarepta denies the allegations in Paragraph 145.

CLAIM VIII
(Infringement of the '217 Patent)

146. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

147. Sarepta denies that Paragraph 147 accurately quotes the language of claim 1 of the '217 patent.

148. Paragraph 148 contains legal conclusions to which no response is required. To the extent a response is required, Sarepta admits that Vyondys 53® is indicated for the treatment of DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping. Sarepta denies any remaining allegations in Paragraph 148.

149. Sarepta admits that Paragraph 149 purports to quote in part from "Highlights of Prescribing Information (Dec. 12, 2019)" and "Highlights of Prescribing Information (Feb. 11, 2021) § 2.4." Sarepta admits that Vyondys 53® is administered via intravenous infusion. Sarepta denies any remaining allegations in Paragraph 149.

150. Sarepta denies the allegations in Paragraph 150.

151. Sarepta denies the allegations in Paragraph 151.

152. Sarepta denies the allegations in Paragraph 152.

153. Sarepta denies the allegations in Paragraph 153.

CLAIM IX
(Infringement of the '322 Patent)

154. Sarepta realleges as if fully set forth herein each of the foregoing paragraphs.

155. Sarepta denies the allegations in Paragraph 155.

156. Sarepta denies the allegations in Paragraph 156.

157. Sarepta denies the allegations in Paragraph 157.

158. Sarepta denies the allegations in Paragraph 158.

159. Sarepta denies the allegations in Paragraph 159.

160. Sarepta denies the allegations in Paragraph 160.

161. Sarepta denies the allegations in Paragraph 161.

162. Sarepta denies the allegations in Paragraph 162.

163. Sarepta denies the allegations in Paragraph 163.

164. Sarepta denies the allegations in Paragraph 164.

Sarepta denies all allegations of the SAC not specifically admitted above.

PRAYER FOR RELIEF

Sarepta denies that Nippon Shinyaku is entitled to the relief it requests or to any other relief.

DEMAND FOR A JURY TRIAL

Sarepta admits that Nippon Shinyaku has demanded a jury trial solely for Claims II-IX of the SAC but denies that it is entitled to one.

DEFENSES

By alleging the Defenses set forth below, Sarepta does not agree or concede that it bears the burden of proof or the burden of persuasion on any of these issues, whether in whole or in part. For its Defenses to the SAC, Sarepta alleges as follows.

First Defense
(No Breach of Contract)

Sarepta has not breached any of its contractual obligations under the MCA.

Second Defense
(The UWA Patents are Not Invalid)

All claims of the UWA Patents are not invalid or unenforceable under 35 U.S.C. § 1 *et seq.*, and Nippon Shinyaku will not be able to demonstrate otherwise by clear and convincing evidence.

Third Defense
(Non-Infringement of the NS Patents)

Sarepta has not infringed and will not infringe, directly or indirectly, any valid and enforceable claim of the NS Patents, either literally or under the doctrine of equivalents.

Fourth Defense
(Invalidity of the NS Patents)

Each asserted claim of the NS Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

Fifth Defense
(Prosecution History Estoppel and Disclaimer)

Nippon Shinyaku's patent infringement claims are estopped in whole or in part by representations made or actions taken during the prosecution of the applications that matured into the NS Patents and/or related patents, under the doctrine of prosecution history estoppel and/or prosecution disclaimer.

Sixth Defense
(Failure to State a Claim)

The SAC fails to state a claim upon which relief may be granted.

Seventh Defense
(No Case or Controversy)

There is no justiciable case or controversy between the parties concerning Claims I-II of the SAC.

Eighth Defense
(Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over Claims I-II of the SAC.

Ninth Defense
(Equitable Defenses and Remedies)

Nippon Shinyaku's breach of contract claim and/or requested remedies are barred in whole or in part under principles of equity, including unclean hands.

For example, in view of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA as detailed in Counterclaim V below, Nippon Shinyaku has unclean hands precluding it from enforcing the MCA and depriving it of any entitlement to injunctive or other equitable relief for any alleged breach of the MCA by Sarepta.

Tenth Defense
(No Damages)

Nippon Shinyaku has incurred no damages as a result of the alleged patent infringement or breach of contract, which Sarepta denies.

Eleventh Defense
(No Injunctive Relief)

Nippon Shinyaku is not entitled to injunctive relief for its breach of contract claim or any other claim because it cannot succeed on the merits of any claim, any alleged injury to Nippon Shinyaku is neither immediate nor irreparable, Nippon Shinyaku has an adequate remedy at law, and the balance of the equities and the public interest are not served by the granting of an injunction. In addition, in view of Nippon Shinyaku's knowing and repeated bad-faith breaches of

the MCA as detailed in Counterclaim V below, Nippon Shinyaku has unclean hands depriving it of any entitlement to injunctive or other equitable relief for any alleged breach of the MCA by Sarepta.

Twelfth Defense
(Limitation on Damages and Costs)

Nippon Shinyaku's claims for relief are barred in whole or in part, including without limitation, by 35 U.S.C. §§ 286, 287, and/or 288.

Thirteenth Defense
(No Willful Infringement)

Nippon Shinyaku is not entitled to enhanced damages pursuant to 35 U.S.C. § 284, because it cannot prove that Sarepta has willfully infringed any valid claim of the NS Patents.

Fourteenth Defense
(No Exceptional Case)

Nippon Shinyaku cannot prove that this is an exceptional case warranting an award of attorney fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power.

Reservation of Additional Defenses

Sarepta reserves any and all additional defenses available under Title 35 of the United States Code, or otherwise in law or equity, now existing, or later arising, as may be developed during discovery or supported by subsequent court rulings.

COUNTERCLAIMS

Counterclaim Plaintiff Sarepta Therapeutics, Inc. ("Sarepta") asserts the following allegations and counterclaims against counterclaim Defendants Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") and NS Pharma, Inc. ("NS Pharma") (collectively "Defendants"). Sarepta reserves the right to assert additional counterclaims as warranted by facts discovered through investigation and discovery.

Nature of the Action

1. Sarepta asserts counterclaims for infringement of U.S. Patent Nos. 9,994,851 ("the '851 patent") (Exhibit A); 10,227,590 ("the '590 patent") (Exhibit B); and 10,266,827 ("the '827 patent") (Exhibit C) (collectively, "the UWA Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. These patent infringement claims arise out of Defendants' unauthorized manufacture, use, sale, offer for sale, and/or importation in the United States of Viltepso, also known as viltolarsen, and Defendants' intentional encouragement of physicians and patients to administer Viltepso.

2. Sarepta further asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent Nos. 9,708,361 ("the '361 patent"); 10,385,092 ("the '092 patent"); 10,407,461 ("the '461 patent"); 10,487,106 ("the '106 patent"); 10,647,741 ("the '741 patent"); 10,662,217 ("the '217 patent"); and 10,683,322 ("the '322 patent") (collectively, "the NS Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

3. Sarepta further asserts a counterclaim for breach of contract arising under Delaware state law.

Parties

4. Sarepta is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 215 First Street, Cambridge, Massachusetts 02142.

5. Nippon Shinyaku represents in its Second Amended Complaint that it is a Japanese company with a principal pace of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

6. Nippon Shinyaku represents in its Second Amended Complaint that by virtue of a license agreement with NCNP, Nippon Shinyaku holds the exclusive assertion rights for the NS Patents.

7. Upon information and belief, NS Pharma is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 149 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. Upon information and belief, NS Pharma is a wholly owned U.S. subsidiary of Nippon Shinyaku. Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso.

Jurisdiction and Venue

8. There is an actual justiciable controversy between Defendants and Sarepta concerning Defendants' liability for infringement of the UWA Patents.

9. Sarepta's counterclaims against Defendants for infringement of the UWA Patents arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

10. This Court has subject matter jurisdiction over the patent infringement counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

11. There is an actual justiciable controversy between Defendants and Sarepta concerning the invalidity of the NS Patents as evidenced by Nippon Shinyaku's allegations in the Second Amended Complaint concerning Sarepta's alleged liability for infringement of the NS Patents.

12. Sarepta's counterclaim for declaratory judgment of invalidity of the NS Patents arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

13. This Court has subject matter jurisdiction over the declaratory judgment counterclaim of invalidity of the NS Patents under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. There is an actual justiciable controversy between Nippon Shinyaku and Sarepta concerning Nippon Shinyaku's breach of contract.

15. Sarepta's breach of contract counterclaim arises under Delaware state law.

16. This Court has subject matter jurisdiction over the breach of contract counterclaim under 28 U.S.C. §§ 1332(a) and 1367(a).

17. Personal jurisdiction is proper over Nippon Shinyaku at least because Nippon Shinyaku has commenced this action and thus submitted to this Court's personal jurisdiction.

18. Upon information and belief, personal jurisdiction is proper over NS Pharma, a Delaware corporation, at least because it has committed acts of infringement of the UWA Patents in Delaware by offering to sell and selling Viltepso (viltolarsen) in the State of Delaware. In addition, upon information and belief, Nippon Shinyaku conferred with, and coordinated with, NS Pharma in bringing this action and thus NS Pharma has consented to this Court's personal jurisdiction.

19. Upon information and belief, Nippon Shinyaku directly or through its agents including its wholly owned U.S. subsidiary NS Pharma, manufactures, markets, offers to sell, sells, and/or distributes Viltepso (viltolarsen) in the State of Delaware and elsewhere in the United States, and Viltepso is prescribed by physicians practicing in Delaware and elsewhere in the United States, is available at pharmacies or medical facilities located within Delaware and elsewhere in the United States, and/or is used by patients in, and/or residents of, Delaware and elsewhere in the United States.

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

The UWA Patents

21. On June 12, 2018, the USPTO issued the '851 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '851 patent is assigned to the University of Western Australia. A copy of the '851 patent is attached hereto as Exhibit A. The '851 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '851 patent for the treatment of muscular dystrophies and the right to enforce the '851 patent.

22. On March 12, 2019, the USPTO issued the '590 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '590 patent is assigned to the University of Western Australia. A copy of the '590 patent is attached hereto as Exhibit B. The '590 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '590 patent for the treatment of muscular dystrophies and the right to enforce the '590 patent.

23. On April 23, 2019, the USPTO issued the '827 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '827 patent is assigned to the University of Western Australia. A copy of the '827 patent is attached hereto as Exhibit C. The '827 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '827 patent for the treatment of muscular dystrophies and the right to enforce the '827 patent.

24. The UWA Patents are listed in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for New Drug Application ("NDA") No. 211970 for Sarepta's Vyondys 53® product, also known as golodirsen. Each of the UWA Patents covers, *inter alia*, an antisense oligonucleotide of 20 to 31

bases wherein a base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195 disclosed in the UWA Patents, in which uracil bases are thymine bases, and a method of using it for the treatment of Duchenne Muscular Dystrophy ("DMD") in patients who have a mutation of the DMD gene that is amenable to exon 53 skipping.

Background

Defendants' Infringing Product

25. Upon information and belief, Defendants' product, Viltepso (viltolarsen), is a morpholino antisense oligonucleotide comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA. Viltepso (viltolarsen) Highlights of Prescribing Information (Aug. 2020),[3] § 11; *see also* Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021)[4]. Viltepso contains 21 bases and CCTCCGGTTCTGAAGGTGTTC as the base sequence. Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021), § 11.

26. Upon information and belief, Viltepso induces exon 53 skipping in a human dystrophin pre-mRNA. *Id.* § 12.1.

27. Upon information and belief, Viltepso is administered to DMD patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping and induces skipping of exon 53 of dystrophin pre-mRNA. *Id.* §§ 1, 12.1. Defendants' label for Viltepso has encouraged and continues to encourage such use.

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[3] Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Aug. 2020), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212154Orig1s000lbl.pdf (last visited Jan. 28, 2022).

[4] Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), https://www.viltepso.com/prescribing-information (last visited Jan. 28, 2022).

28. Upon information and belief, Defendants conducted pre-clinical and clinical development of Viltepso (viltolarsen), including clinical trials, to generate data in support of their submission of an NDA with the FDA for Viltepso (viltolarsen).

29. Upon information and belief, on October 2, 2019, Nippon Shinyaku announced that it had submitted a rolling NDA for Viltepso (viltolarsen) with the FDA. Nippon Shinyaku News Release (Oct. 2, 2019).[5]

30. On August 12, 2020, the FDA announced it had granted accelerated approval to Viltepso for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. FDA News Release (Aug. 12, 2020).[6]

31. Upon information and belief, Nippon Shinyaku announced that NS Pharma, a wholly owned U.S. subsidiary of Nippon Shinyaku, had launched Viltepso for commercial sales in the United States as of August 19, 2020. Nippon Shinyaku News Release (Aug. 20, 2020).[7] Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso. *Id.*

32. Upon information and belief, since at least August 2020, Defendants have encouraged physicians to treat DMD patients by administering Viltepso to induce skipping of exon 53 of dystrophin pre-mRNA including through their labels for Viltepso. Defendants have also facilitated pricing and reimbursement of Viltepso in the United States.

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[5] Nippon Shinyaku Press Release (Oct. 2, 2019), https://www.nippon-shinyaku.co.jp/file/download.php?file_id=3838 (last visited Jan. 28, 2022).

[6] FDA News Release (Aug. 12, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last visited Jan. 28, 2022).

[7] Nippon Shinyaku Press Release (Aug. 20, 2020), https://www.nippon-shinyaku.co.jp/file/download.php?file_id=3868 (last visited Jan. 28, 2022).

Defendants' Awareness of the UWA Patents

33. Upon information and belief, Defendants have been familiar with and knew of the UWA Patents prior to this litigation. Upon information and belief, Defendants believed prior to this litigation that one or more claims of the UWA Patents covered Viltepso (viltolarsen). When the UWA Patents issued in 2018 and 2019, for example, Defendants' NDA seeking marketing approval for viltolarsen was under regulatory review in the United States. Upon information and belief, Defendants became aware of the UWA Patents after the UWA Patents were submitted for listing in the FDA Orange Book for Vyondys 53® in December 2019. Upon information and belief, Defendants expected that their Viltepso (viltolarsen) product, if approved, would compete directly with Sarepta's Vyondys 53® (golodirsen) product. Upon information and belief, Defendants learned of the UWA Patents through their efforts to research and/or monitor third-party U.S. patents that could potentially interfere with their ability to market Viltepso (viltolarsen) in the United States.

34. Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement ("MCA") effective June 1, 2020. Upon information and belief, Defendants were already aware of the UWA Patents when Sarepta and Nippon Shinyaku began business discussions under the MCA in June 2020.

COUNTERCLAIM I
(Infringement of the '851 Patent)

35. Sarepta realleges each of the foregoing Paragraphs 1-34 as if fully set forth herein.

36. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

37. Claim 1 of the '851 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

38. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the '851 patent.

39. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

40. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. *Id.* § 12.1.

41. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

42. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

43. Upon information and belief, Defendants knew or should have known of the existence of the '851 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '851 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '851 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

44. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '851 patent.

45. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id*. Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '851 patent.

46. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

47. Upon information and belief, Defendants' infringement of the '851 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct

related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '851 patent.

48. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

COUNTERCLAIM II
(Infringement of the '590 Patent)

49. Sarepta realleges each of the foregoing Paragraphs 1-48 as if fully set forth herein.

50. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint as if fully set forth herein.

51. Claim 1 of the '590 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

52. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the '590 patent.

53. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

54. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with a genetic mutation that is amenable to exon 53 skipping. *Id.* § 12.1.

55. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

56. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

57. Upon information and belief, Defendants knew or should have known of the existence of the '590 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '590 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '590 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

58. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, viltolarsen has no substantial non-infringing uses, and Defendants know that viltolarsen is especially made or especially adapted for use in infringement of the '590 patent.

59. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and

instructs physicians and patients to use Viltepso to treat DMD. *Id*. Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '590 patent.

60. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

61. Upon information and belief, Defendants' infringement of the '590 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '590 patent.

62. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

COUNTERCLAIM III
(Infringement of the '827 Patent)

63. Sarepta realleges each of the foregoing Paragraphs 1-62 as if fully set forth herein.

64. Sarepta incorporates by reference its answer and responses to Nippon Shinyaku's Second Amended Complaint as if fully set forth herein.

65. Claim 1 of the '827 patent recites:

> A method for treating a patient with Duchenne muscular dystrophy (DMD) in need thereof who has a mutation of the DMD gene that is amenable to exon 53 skipping, comprising administering to the patient an antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense

> oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

66. Upon information and belief, the use of Viltepso satisfies each element of, and directly infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '827 patent.

67. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1.

68. Upon information and belief, Defendants knew or should have known of the existence of the '827 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '827 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '827 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

69. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id*. Upon information and belief, viltolarsen has no substantial non-infringing uses, and Defendants know that viltolarsen is especially made or especially adapted for use in infringement of the '827 patent.

70. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id*. Upon information and belief,

Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '827 patent.

71. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '827 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

72. Upon information and belief, Defendants' infringement of the '827 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '827 patent.

73. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

COUNTERCLAIM IV
(Declaration of Invalidity of the NS Patents)

74. Sarepta realleges each of the foregoing Paragraphs 1-73 as if fully set forth herein.

75. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint.

76. Each claim of the NS Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

77. By way of example, the claims of the NS Patents are invalid under 35 U.S.C. §§ 102 and/or 103 in view of Popplewell, L.J., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials*,

Neuromuscular Disorders 20:102–110 (2010) ("Popplewell") and Sazani, P., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658*, Int'l J. Toxicology 29(2):143–156 (2010) ("Sazani"), alone or in combination with other prior art, for at least the reasons set forth in Sarepta's IPR Petitions challenging the NS Patents. In granting Sarepta's IPR Petitions challenging all claims of all seven NS Patents, for example, the Patent Trial and Appeal Board found Sarepta's arguments and evidence of unpatentability persuasive, concluding in each institution decision that Sarepta "has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable." *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, Decisions Granting Institution in IPR2021-01134, Paper No. 20 (Jan. 12, 2022); IPR2021-01135, Paper No. 20 (Jan. 12, 2022); IPR2021-01136, Paper No. 19 (Jan. 13, 2022); IPR2021-01137, Paper No. 18 (Jan. 13, 2022); IPR2021-01138, Paper No. 18 (Jan. 13, 2022); IPR2021-01139, Paper No. 18 (Jan. 13, 2022); and IPR2021-01140, Paper No. 18 (Jan. 12, 2022).

78. An actual case or controversy exists between Sarepta and Defendants as to whether the claims of the NS Patents are invalid.

79. Sarepta is entitled to a declaratory judgment that the claims of the NS Patents are invalid.

80. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

COUNTERCLAIM V
(Breach of Contract)

81. Sarepta realleges each of the foregoing Paragraphs 1-80 as if fully set forth herein.

82. Sarepta incorporates by reference its answers and responses in Sarepta's Answer and Counterclaims to Nippon Shinyaku's Second Amended Complaint as fully set forth herein.

83. Sarepta asserts a claim for breach of contract arising under Delaware state law. This Court has subject matter jurisdiction over this breach of contract claim under 28 U.S.C. §§ 1332(a) and 1367(a).

84. This claim for breach of contract arises out of Nippon Shinyaku's material breach of the MCA with Sarepta.

85. Properly interpreted, the MCA is a valid and enforceable contract between Sarepta and Nippon Shinyaku.

86. Sections 1-3 of the MCA define "Confidential Information" and proscribe improper disclosures or uses of confidential information beyond the permitted purposes. Section 2.2, entitled "Obligations of Confidentiality and Non-Use," states among other relevant provisions that:

> The Parties intend and agree that this Agreement, the Proposed Transaction and all disclosures, including all meetings, discussions, correspondence, communications, documents, or other materials exchanged between the Parties made in connection with this Agreement and the Proposed Transaction shall not be submitted, referenced, admitted or otherwise used by the Recipient, its Affiliates, or their respective Representatives against the other Party in any legal action, except in an action to enforce the terms of this Agreement, and shall be treated as conducted in the aid of negotiation and shall be governed by and entitled to the protections and privileges of Delaware Rule of Evidence 408 and Federal Rule of Evidence 408, as well as any and all analogous or applicable privileges or additional limitations on use and disclosure set forth herein. Furthermore, regardless of whether the Proposed Transaction leads to any arrangement or resolution of issues, the fact that these confidential Proposed Transactions occurred shall not be referenced in any legal action currently pending, including but not limited to the EP Oppositions, the JP Actions, or the Potential Actions. Neither Party nor their Affiliates or Representatives shall in any way attempt to place into evidence any document, fact, statement or opinion in any way relating to the Proposed Transaction for any purpose, regardless of whether such document, fact, statement or opinion would be admissible under FRE 408 or any other analogous or applicable privilege.

D.I. 2-1 at 3.

87. On July 14, 2021, Nippon Shinyaku filed its original Complaint in this action containing confidential information in violation of its agreement, materially breaching its obligations under the MCA, Sections 1-3.

88. Notwithstanding that in its first set of Rule 12 responsive motions Sarepta raised its objection to such confidential information appearing in Nippon Shinyaku's original Complaint contrary to the terms of the MCA, Nippon Shinyaku again included the same confidential material in its First Amended Complaint ("FAC"), filed September 10, 2021 (D.I. 39).

89. Sarepta renewed its objection in subsequent Rule 12 responsive motions (D.I. 53, 54) to such confidential information appearing in Nippon Shinyaku's FAC contrary to the terms of the MCA.

90. On December 20, 2021, the Court found that Nippon Shinyaku had violated the confidentiality and non-use provisions of the MCA and struck from the FAC the second sentence of paragraph 2 as well as paragraphs 11, 78, and 91 of the FAC. (Hearing Tr. at 31-34; D.I. 84.)

91. As the Court found, Nippon Shinyaku "agreed not to hold the parties' confidential communications against Sarepta in future litigation" because the terms of the valid and enforceable MCA had prohibitions against mentioning confidential communications in legal actions. *Id*. at 32, 34. But Nippon Shinyaku materially breached the terms of the agreement by including confidential information in its original Complaint and again in its FAC, even after being put on notice of its breach, requiring further briefing, motions practice, and a ruling by this Court striking the confidential information from Nippon Shinyaku's pleading.

92. Sarepta has suffered prejudice and injury by virtue of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA's confidentiality and non-use provisions of Section 2, entitling Sarepta to damages in an amount exceeding $75,000.

93. In addition, in view of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA, Nippon Shinyaku has unclean hands precluding enforcement of the MCA and depriving it of any entitlement to injunctive or other equitable relief for any alleged breach of the MCA by Sarepta.

PRAYER FOR RELIEF

WHEREFORE, Sarepta respectfully requests that the Court enter judgment in its favor and against Defendants on the counterclaims set forth above and respectfully requests that this Court:

1. award Sarepta the relief it seeks in its Defenses asserted in response to Nippon Shinyaku's Second Amended Complaint for Breach of Contract, Declaratory Judgment of Invalidity, and Patent Infringement;

2. deny all damages, costs, expenses, attorneys' fees, or other relief requested by Nippon Shinyaku;

3. enter judgment that the '851 patent has been infringed and will be infringed by Defendants, pursuant to at least 35 U.S.C. §§ 271(a), (b), and/or (c), either literally and/or under the doctrine of equivalents;

4. enter judgment that the '590 patent has been infringed and will be infringed by Defendants, pursuant to at least 35 U.S.C. §§ 271(a), (b), and/or (c), either literally and/or under the doctrine of equivalents;

5. enter judgment that the '827 patent has been infringed and will be infringed by Defendants, pursuant to 35 U.S.C. §§ 271(b) and/or (c), either literally and/or under the doctrine of equivalents;

6. to the extent that Defendants have or will commercially manufacture, use, offer for sale, or sell Viltepso within the United States or import Viltepso into the United States, prior to the expiration of the UWA Patents, including any extensions, enter judgment awarding Sarepta monetary relief pursuant to 35 U.S.C. § 284, together with interest;

7. enter judgment that Defendants' infringement of the UWA Patents has been willful, and/or an order increasing any damages awarded for Defendants' infringement of the UWA Patents pursuant to 35 U.S.C. § 284;

8. declare that Sarepta has not infringed and will not infringe any claim of the NS Patents;

9. declare that each claim of the NS Patents is invalid;

10. find that Nippon Shinyaku has knowingly, materially, and repeatedly breached the MCA's confidentiality and non-use provisions in bath faith and that those bad-faith breaches of the MCA constitute unclean hands, precluding Nippon Shinyaku from enforcing the MCA or obtaining injunctive or other equitable relief for any alleged breach of the MCA by Sarepta;

11. declare that this is an exceptional case under 35 U.S.C. § 285 and award Sarepta its attorneys' fees, expenses, and costs; and

12. award all other and further relief the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(c), Sarepta hereby demands a trial by jury on all triable issues alleged in its counterclaims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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January 28, 2022

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 28, 2022, upon the following in the manner indicated:

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Megan E. Dellinger (#5739)

Exhibit III

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1015 (LPS)
	)	
SAREPTA THERAPEUTICS, INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

SAREPTA THERAPEUTICS, INC.,

Defendant and Counter-Plaintiff

v.

NIPPON SHINYAKU CO., LTD. and
NS PHARMA, INC.

Plaintiff and Counter-Defendants.

COUNTER-DEFENDANTS' ANSWER TO COUNTER-PLAINTIFF'S COUNTERCLAIMS

Counter-Defendants Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") and NS Pharma, Inc. ("NS Pharma") (collectively, "Counter-Defendants"), by their attorneys, answer the Counterclaims of Counter-Plaintiff Sarepta Therapeutics, Inc. ("Sarepta") as follows:

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE NATURE OF THE ACTION

1. Sarepta asserts counterclaims for infringement of U.S. Patent Nos. 9,994,851 ("the '851 patent") (Exhibit A); 10,227,590 ("the '590 patent") (Exhibit B); and 10,266,827 ("the '827 patent") (Exhibit C) (collectively, "the UWA Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. These patent infringement claims arise out of Defendants' unauthorized manufacture, use, sale, offer for sale, and/or importation in the United States of Viltepso, also known as viltolarsen, and Defendants' intentional encouragement of physicians and patients to administer Viltepso.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert claims for infringement of the '851 Patent, the '590 Patent, and the '827 Patent. Counter-Defendants deny the remaining allegations in paragraph 1.

2. Sarepta further asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent Nos. 9,708,361 ("the '361 patent"); 10,385,092 ("the '092 patent"); 10,407,461 ("the '461 patent"); 10,487,106 ("the '106 patent"); 10,647,741 ("the '741 patent"); 10,662,217 ("the '217 patent"); and 10,683,322 ("the '322 patent") (collectively, "the NS Patents") arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert claims for declaratory judgment of invalidity of the '361 Patent, the '092 Patent, the '461 Patent, the '106 Patent, the '741 Patent, the '217 Patent, and the '322 Patent. Counter-Defendants deny the remaining allegations in paragraph 2.

3. Sarepta further asserts a counterclaim for breach of contract arising under Delaware state law.

ANSWER: Counter-Defendants admit that Sarepta's counterclaims purport to assert a claim for breach of contract arising under Delaware state law. Counter-Defendants deny the remaining allegations in paragraph 3.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE PARTIES

4. Sarepta is a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 215 First Street, Cambridge, Massachusetts 02142.

ANSWER: On information and belief, admitted.

5. Nippon Shinyaku represents in its Second Amended Complaint that it is a Japanese company with a principal pace of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

ANSWER: Counter-Defendants admit the allegations in paragraph 5.

6. Nippon Shinyaku represents in its Second Amended Complaint that by virtue of a license agreement with NCNP, Nippon Shinyaku holds the exclusive assertion rights for the NS Patents.

ANSWER: Counter-Defendants admit the allegations in paragraph 6.

7. Upon information and belief, NS Pharma is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 149 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. Upon information and belief, NS Pharma is a wholly owned U.S. subsidiary of Nippon Shinyaku. Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso.

ANSWER: Counter-Defendants admit that NS Pharma is a corporation organized and existing under the laws of the State of Delaware. Counter-Defendants further admit that NS Pharma is a wholly-owned subsidiary of Nippon Shinyaku and that NS Pharma is Nippon Shinyaku's U.S. Agent authorized by FDA to market Viltepso. Counter-Defendants admit that NS Pharma has a principal place of business at 140 East Ridgewood Ave., Suite 280S, Paramus, NJ 07652. Counter-Defendants deny the remaining allegations in paragraph 7.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING JURISDICTION AND VENUE

8. There is an actual justiciable controversy between Defendants and Sarepta concerning Defendants' liability for infringement of the UWA Patents.

ANSWER: Counter-Defendants admit that an actual justiciable controversy exists between Counter-Defendants and Sarepta regarding Sarepta's allegations that Counter-Defendants infringe the UWA Patents. Counter-Defendants deny liability for infringement of the UWA Patents and deny the remaining allegations in paragraph 8.

9. Sarepta's counterclaims against Defendants for infringement of the UWA Patents arise under the patent laws of the United States, 35 U.S.C. § 1 et seq.

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims against Counter-Defendants for infringement of the UWA Patents arise under the patent laws of the

United States, 35 U.S.C. § 1 et seq. Counter-Defendants deny the remaining allegations in paragraph 9.

10. This Court has subject matter jurisdiction over the patent infringement counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that the Court has subject matter jurisdiction over the patent infringement counterclaims under 28 U.S.C. §§ 1331 and 1338(a). Counter-Defendants deny any allegations of infringement of the UWA Patents and deny the remaining allegations in paragraph 10.

11. There is an actual justiciable controversy between Defendants and Sarepta concerning the invalidity of the NS Patents as evidenced by Nippon Shinyaku's allegations in the Second Amended Complaint concerning Sarepta's alleged liability for infringement of the NS Patents.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that there is an actual justiciable controversy between Counter-Defendants and Sarepta concerning the invalidity of the NS Patents as evidenced by Nippon Shinyaku's allegations in the Second Amended Complaint concerning Sarepta's liability for infringement of the NS Patents. Counter-Defendants deny the remaining allegations in paragraph 11.

12. Sarepta's counterclaim for declaratory judgment of invalidity of the NS Patents arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaim for declaratory judgment of invalidity of the NS Patents arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. and under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq. Counter-Defendants deny the remaining allegations in paragraph 12.

13. This Court has subject matter jurisdiction over the declaratory judgment counterclaim of invalidity of the NS Patents under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that this Court has subject matter jurisdiction over the declaratory judgment counterclaim of invalidity of the NS Patents under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Counter-Defendants deny the remaining allegations in paragraph 13.

14. There is an actual justiciable controversy between Nippon Shinyaku and Sarepta concerning Nippon Shinyaku's breach of contract.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim. Counter-Defendants deny the remaining allegations in paragraph 14.

15. Sarepta's breach of contract counterclaim arises under Delaware state law.

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim under Delaware law. Counter-Defendants deny the remaining allegations in paragraph 15.

16. This Court has subject matter jurisdiction over the breach of contract counterclaim under 28 U.S.C. §§ 1332(a) and 1367(a).

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim. Counter-Defendants deny the remaining allegations in paragraph 16.

17. Personal jurisdiction is proper over Nippon Shinyaku at least because Nippon Shinyaku has commenced this action and thus submitted to this Court's personal jurisdiction.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that personal jurisdiction is proper over Nippon Shinyaku for purposes of this action only at least because Nippon Shinyaku has commenced this action and thus submitted to this Court's personal jurisdiction. Counter-Defendants deny the remaining allegations in paragraph 17.

18. Upon information and belief, personal jurisdiction is proper over NS Pharma, a Delaware corporation, at least because it has committed acts of infringement of the UWA Patents in Delaware by offering to sell and selling Viltepso (viltolarsen) in the State of Delaware. In addition, upon information and belief, Nippon Shinyaku conferred with, and coordinated with, NS Pharma in bringing this action and thus NS Pharma has consented to this Court's personal jurisdiction.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that personal jurisdiction is proper over NS Pharma for purposes of this action only. Counter-Defendants deny the remaining allegations in paragraph 18.

19. Upon information and belief, Nippon Shinyaku directly or through its agents including its wholly owned U.S. subsidiary NS Pharma, manufactures, markets, offers to sell, sells, and/or distributes Viltepso (viltolarsen) in the State of Delaware and elsewhere in the United States, and Viltepso is prescribed by physicians practicing in Delaware and elsewhere in the United States, is available at pharmacies or medical facilities located within Delaware and elsewhere in the United States, and/or is used by patients in, and/or residents of, Delaware and elsewhere in the United States.

ANSWER: Counter-Defendants admit that Nippon Shinyaku directly or through its agents and other third parties manufactures, markets, offers to sell, sells, and/or distributes Viltepso (viltolarsen) in the United States. Counter-Defendants also admit that Viltepso is prescribed by physicians practicing in the United States, is available at pharmacies or medical facilities in the United States, and/or is used by patients in, and/or residents of, Delaware and

elsewhere in the United States. Counter-Defendants deny the remaining allegations in paragraph 19.

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that venue is proper in this Court for purposes of this action only. Counter-Defendants deny the remaining allegations in paragraph 20.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING THE UWA PATENTS

21. On June 12, 2018, the USPTO issued the '851 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '851 patent is assigned to the University of Western Australia. A copy of the '851 patent is attached hereto as Exhibit A. The '851 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '851 patent for the treatment of muscular dystrophies and the right to enforce the '851 patent.

ANSWER: Counter-Defendants admit that the '851 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it issued on June 12, 2018. Counter-Defendants further admit that the face of the '851 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit A purports to be a copy of the '851 patent. Counter-Defendants deny that the '851 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21 and therefore deny the same.

22. On March 12, 2019, the USPTO issued the '590 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '590 patent is assigned to the University of Western Australia. A copy of the '590 patent is attached hereto as Exhibit B. The '590 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '590 patent for the treatment of muscular dystrophies and the right to enforce the '590 patent.

ANSWER: Counter-Defendants admit that the '590 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it

issued on March 12, 2019. Counter-Defendants further admit that the face of the '590 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit B purports to be a copy of the '590 patent. Counter-Defendants deny that the '590 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 22 and therefore deny the same.

23. On April 23, 2019, the USPTO issued the '827 patent, entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof." The '827 patent is assigned to the University of Western Australia. A copy of the '827 patent is attached hereto as Exhibit C. The '827 patent is fully maintained and is valid and enforceable. Sarepta has exclusive rights to the '827 patent for the treatment of muscular dystrophies and the right to enforce the '827 patent.

ANSWER: Counter-Defendants admit that the '827 patent is entitled "Antisense Oligonucleotides for Inducing Exon Skipping and Methods of Use Thereof" and states that it issued on April 23, 2019. Counter-Defendants further admit that the face of the '827 patent lists the Assignee as the University of Western Australia and that Sarepta's Exhibit C purports to be a copy of the '827 patent. Counter-Defendants deny that the '827 patent is valid and enforceable. Counter-Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 23 and therefore deny the same.

24. The UWA Patents are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 211970 for Sarepta's Vyondys 53® product, also known as golodirsen. Each of the UWA Patents covers, inter alia, an antisense oligonucleotide of 20 to 31 bases wherein a base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195 disclosed in the UWA Patents, in which uracil bases are thymine bases, and a method of using it for the treatment of Duchenne Muscular Dystrophy ("DMD") in patients who have a mutation of the DMD gene that is amenable to exon 53 skipping.

ANSWER: Counter-Defendants admit that the UWA Patents are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 211970 for Sarepta's Vyondys 53® product, also known as golodirsen. Counter-Defendants further admit that each of

the claims in the UWA Patents claims, inter alia, an antisense oligonucleotide of 20 to 31 bases, wherein the base sequence comprises at least 12 consecutive bases of SEQ ID NO: 195 in which uracil bases are thymine bases. Counter-Defendants further admit that the claims of the '827 patent claim a method for treating a patient with DMD in need thereof who has a mutation of the DMD gene that is amenable to exon 53 skipping. Counter-Defendants deny the remaining allegations in paragraph 24.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING DEFENDANTS' INFRINGING PRODUCT[1]

25. Upon information and belief, Defendants' product, Viltepso (viltolarsen), is a morpholino antisense oligonucleotide comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA. Viltepso (viltolarsen) Highlights of Prescribing Information (Aug. 2020), § 11; *see also* Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021). Viltepso contains 21 bases and CCTCCGGTTCTGAAGGTGTTC as the base sequence. Viltepso (viltolarsen) Highlights of Prescribing Information (Mar. 2021), § 11.

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "Viltolarsen contains 21 linked subunits." Counter-Defendants further admit that the sequence of bases of Viltepso from the 5' end to the 3' end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 25.

[1] Counter-Defendants have adopted the headings as provided in Sarepta's Counterclaims for ease of reference only. Counter-Defendants do not admit any allegation found in any of the headings and deny that their product is "infringing."

26. Upon information and belief, Viltepso induces exon 53 skipping in a human dystrophin pre-mRNA. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that § 12.1 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 26.

27. Upon information and belief, Viltepso is administered to DMD patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping and induces skipping of exon 53 of dystrophin pre-mRNA. *Id.* §§ 1, 12.1. Defendants' label for Viltepso has encouraged and continues to encourage such use.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of August 2020 and with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping," and § 12.1 states "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 27.

28. Upon information and belief, Defendants conducted pre-clinical and clinical development of Viltepso (viltolarsen), including clinical trials, to generate data in support of their submission of an NDA with the FDA for Viltepso (viltolarsen).

ANSWER: Counter-Defendants admit that Nippon Shinyaku conducted pre-clinical and clinical development of Viltepso (viltolarsen), including clinical trials, to generate data in support of the submission of an NDA with the FDA for Viltepso (viltolarsen). Counter-Defendants deny that NS Pharma was involved in the pre-clinical development of Viltepso. Counter-Defendants deny the remaining allegations in paragraph 28.

29. Upon information and belief, on October 2, 2019, Nippon Shinyaku announced that it had submitted a rolling NDA for Viltepso (viltolarsen) with the FDA. Nippon Shinyaku News Release (Oct. 2, 2019).

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "U.S. FDA Submission of New Drug Application for NS-065/NCNP-01 (viltolarsen)" dated October 2, 2019 states that Nippon Shinyaku "announced that it has completed the submission of its rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for NS-065/NCNP-01 (viltolarsen)." Counter-Defendants deny the remaining allegations in paragraph 29.

30. On August 12, 2020, the FDA announced it had granted accelerated approval to Viltepso for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. FDA News Release (Aug. 12, 2020).

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "FDA Approves Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation" dated August 12, 2020 states that "[t]oday, the U.S. Food and Drug Administration granted accelerated approval to Viltepso (viltolarsen) injection for the treatment of Duchenne muscular dystrophy (DMD) in patients wo have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 30.

31. Upon information and belief, Nippon Shinyaku announced that NS Pharma, a wholly owned U.S. subsidiary of Nippon Shinyaku, had launched Viltepso for commercial sales in the United States as of August 19, 2020. Nippon Shinyaku News Release (Aug. 20, 2020). Upon information and belief, NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso. *Id*.

ANSWER: Counter-Defendants admit that the article cited in Sarepta's counterclaims titled "VILTEPSO™ (viltolarsen) injection Now Commercially Available in the U.S." dated August 20, 2020 states that "Nippon Shinyaku Co., Ltd. . . . announced today that NS Pharma, Inc. . . . a wholly owned subsidiary of Nippon Shinyaku made VILTEPSO™ (viltolarsen) now available for commercial sales in the United States market as of August 19 (EST)." Counter-Defendants further admit that NS Pharma is Nippon Shinyaku's U.S. Agent authorized by the FDA to market Viltepso. Counter-Defendants deny the remaining allegations in paragraph 31.

32. Upon information and belief, since at least August 2020, Defendants have encouraged physicians to treat DMD patients by administering Viltepso to induce skipping of exon 53 of dystrophin pre-mRNA including through their labels for Viltepso. Defendants have also facilitated pricing and reimbursement of Viltepso in the United States.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Counter-Defendants deny the remaining allegations in paragraph 32.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING DEFENDANTS' AWARENESS OF THE UWA PATENTS

33. Upon information and belief, Defendants have been familiar with and knew of the UWA Patents prior to this litigation. Upon information and belief, Defendants believed prior to this litigation that one or more claims of the UWA Patents covered Viltepso (viltolarsen). When the UWA Patents issued in 2018 and 2019, for example, Defendants' NDA seeking marketing approval for viltolarsen was under regulatory review in the United States. Upon information and belief, Defendants became aware of the UWA Patents after the UWA Patents were submitted for listing in the FDA Orange Book for Vyondys 53® in December 2019. Upon information and belief, Defendants expected that their Viltepso (viltolarsen) product, if approved, would compete directly with Sarepta's Vyondys 53® (golodirsen) product. Upon information and belief,

Defendants learned of the UWA Patents through their efforts to research and/or monitor third-party U.S. patents that could potentially interfere with their ability to market Viltepso (viltolarsen) in the United States.

ANSWER: Counter-Defendants admit that they were aware of the UWA Patents by at least September 2019. Counter-Defendants further admit that the UWA Patents include claims aimed at capturing VILTEPSO. Counter-Defendants admit that the NDA seeking marketing approval for viltolarsen was under regulatory review in the United States in 2018 and 2019. Counter-Defendants further admit that Nippon Shinyaku and Sarepta are direct competitors in certain markets for antisense oligonucleotide-based therapies for the treatment of DMD. Counter-Defendants deny the remaining allegations in paragraph 33.

34. Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement ("MCA") effective June 1, 2020. Upon information and belief, Defendants were already aware of the UWA Patents when Sarepta and Nippon Shinyaku began business discussions under the MCA in June 2020.

ANSWER: Counter-Defendants admit that Sarepta and Nippon Shinyaku entered into a Mutual Confidentiality Agreement ("MCA") effective June 1, 2020. Counter-Defendants further admit that they were aware of the UWA Patents at least as of September 2019. Counter-Defendants deny the remaining allegations in paragraph 34.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM I (Infringement of the '851 Patent)

35. Sarepta realleges each of the foregoing Paragraphs 1-34 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-34 as if fully set forth herein.

36. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

37. Claim 1 of the ’851 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69), wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 37 quotes claim 1 of the ’851 patent.

38. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the ’851 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 38.

39. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states “Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass.” Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states “Viltolarsen contains 21 linked subunits.” Counter-Defendants further admit that the sequence of bases of Viltepso from the 5’ end to the 3’ end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 39.

40. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 12.1 that "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 40.

41. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 41.

42. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

ANSWER: Counter-Defendants deny the allegations in paragraph 42.

43. Upon information and belief, Defendants knew or should have known of the existence of the '851 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '851 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '851 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '851 Patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 43.

44. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '851 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 44.

45. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '851 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 45.

46. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 46.

47. Upon information and belief, Defendants' infringement of the '851 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '851 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 47.

48. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 48.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM II (Infringement of the '590 Patent)

49. Sarepta realleges each of the foregoing Paragraphs 1-48 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-48 as if fully set forth herein.

50. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

51. Claim 1 of the '590 patent recites:

> An antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 51 quotes claim 1 of the '590 patent.

52. Upon information and belief, Viltepso satisfies each element of at least claim 1 of the '590 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 52.

53. Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 11. Viltolarsen contains 21 linked subunits. *Id.* The base sequence of viltolarsen is CCTCCGGTTCTGAAGGTGTTC, which includes CTGAAGGTGTTC as 12 consecutive bases. *Id.*

ANSWER: Counter-Defendants admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass." Counter-Defendants also admit that § 11 of the Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states "Viltolarsen contains 21 linked subunits." Counter-Defendants further admit that the sequence of bases of Viltepso from the 5' end to the 3' end is CCTCCGGTTCTGAAGGTGTTC. Counter-Defendants deny the remaining allegations in paragraph 53.

54. Viltepso is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. *Id.* § 12.1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 12.1 that "VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin

protein in patients with genetic mutations that are amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 54.

55. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id.* § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 55.

56. Upon information and belief, Defendants have directly infringed and continue to directly infringe at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Viltepso in the United States in violation of 35 U.S.C. § 271(a).

ANSWER: Counter-Defendants deny the allegations in paragraph 56.

57. Upon information and belief, Defendants knew or should have known of the existence of the '590 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '590 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '590 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '590 Patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 57.

58. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '590 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a

confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 58.

59. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '590 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 59.

60. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '590 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 60.

61. Upon information and belief, Defendants' infringement of the '590 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '590 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 61.

62. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 62.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM III (Infringement of the '827 Patent)

63. Sarepta realleges each of the foregoing Paragraphs 1-62 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-62 as if fully set forth herein.

64. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

65. Claim 1 of the '827 patent recites:

> A method for treating a patient with Duchenne muscular dystrophy (DMD in need thereof who has a mutation of the DMD gene that is amenable to exon 53 skipping, comprising administering to the patient an antisense oligonucleotide of 20 to 31 bases comprising a base sequence that is 100% complementary to consecutive bases of a target region of exon 53 of the human dystrophin pre-mRNA, wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID NO: 195), in which uracil bases are thymine bases, wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide, and wherein the antisense oligonucleotide induces exon 53 skipping; or a pharmaceutically acceptable salt thereof.

ANSWER: Counter-Defendants admit that paragraph 65 quotes claim 1 of the '827 patent.

66. Upon information and belief, the use of Viltepso satisfies each element of, and directly infringes, either literally or under the doctrine of equivalents, at least claim 1 of the '827 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 66.

67. Viltepso is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *See* Viltepso (viltolarsen) Highlights of Prescribing Information (Rev. Mar. 2021), § 1.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is

indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 67.

68. Upon information and belief, Defendants knew or should have known of the existence of the '827 patent at least as of the date of its issuance. For example, upon information and belief, Defendants learned of the '827 patent through their monitoring of third-party patent rights, including the UWA Patents, and their efforts to obtain approval for, and market, viltolarsen in the United States. Upon information and belief, Defendants were aware of the '827 patent before June 2020 when Nippon Shinyaku and Sarepta began business discussions under the MCA.

ANSWER: Counter-Defendants admit that they were aware of the '827 patent by at least September 2019. Counter-Defendants deny the remaining allegations in paragraph 68.

69. Viltepso is approved for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. *Id*. Upon information and belief, Viltepso has no substantial non-infringing uses, and Defendants know that Viltepso is especially made or especially adapted for use in infringement of the '827 patent.

ANSWER: Counter-Defendants admit that Viltepso (viltolarsen) Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 69.

70. Upon information and belief, Defendants' sale, offer for sale, and/or distribution of Viltepso includes labeling indicating that it is approved by the FDA to treat DMD in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping and instructs physicians and patients to use Viltepso to treat DMD. *Id.* Upon information and belief, Defendants specifically intend that Viltepso be used to treat DMD with the knowledge that it would infringe the '827 patent.

ANSWER: Counter-Defendants admit that Viltepso is sold, offered for sale, and/or distributed in the United States and that its Highlights of Prescribing Information with a revision date of March 2021 states in § 1 that "VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is

amenable to exon 53 skipping." Counter-Defendants deny the remaining allegations in paragraph 70.

71. Upon information and belief, Defendants have induced and/or contributed to and continue to induce and/or contribute to infringement of at least claim 1 of the '827 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Counter-Defendants deny the allegations in paragraph 71.

72. Upon information and belief, Defendants' infringement of the '827 patent has been willful and continues to be willful, entitling Sarepta to enhanced damages pursuant to 35 U.S.C. § 284. Upon information and belief, Defendants knew or should have known that their conduct related to the development, manufacture, use, offer for sale, sale, and/or importation of Viltepso constituted an unreasonable risk of infringement of at least claim 1 of the '827 patent.

ANSWER: Counter-Defendants deny the allegations in paragraph 72.

73. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations in paragraph 73.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM IV (Declaration of Invalidity of the NS Patents)

74. Sarepta realleges each of the foregoing Paragraphs 1-73 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-73 as if fully set forth herein.

75. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

76. Each claim of the NS Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

ANSWER: Counter-Defendants deny the allegations in paragraph 76.

77. By way of example, the claims of the NS Patents are invalid under 35 U.S.C. §§ 102 and/or 103 in view of Popplewell, L.J., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials,* Neuromuscular Disorders 20:102–110 (2010) ("Popplewell") and Sazani, P., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658,* Int'l J. Toxicology 29(2):143–156 (2010) ("Sazani"), alone or in combination with other prior art, for at least the reasons set forth in Sarepta's IPR Petitions challenging the NS Patents. In granting Sarepta's IPR Petitions challenging all claims of all seven NS Patents, for example, the Patent Trial and Appeal Board found Sarepta's arguments and evidence of unpatentability persuasive, concluding in each institution decision that Sarepta "has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable." *See Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.,* Decisions Granting Institution in IPR2021-01134, Paper No. 20 (Jan. 12, 2022); IPR2021-01135, Paper No. 20 (Jan. 12, 2022); IPR2021-01136, Paper No. 19 (Jan. 13, 2022); IPR2021-01137, Paper No. 18 (Jan. 13, 2022); IPR2021-01138, Paper No. 18 (Jan. 13, 2022); IPR2021-01139, Paper No. 18 (Jan. 13, 2022); and IPR2021-01140, Paper No. 18 (Jan. 12, 2022).

ANSWER: Counter-Defendant admits that the Patent Trial and Appeal Board stated in the Institution Decisions for the IPR Petitions that Sarepta "has demonstrated a reasonable likelihood of success in proving that the challenged claims of the [patent] are unpatentable." Counter-Defendants deny the remaining allegations in paragraph 77.

78. An actual case or controversy exists between Sarepta and Defendants as to whether the claims of the NS Patents are invalid.

ANSWER: Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that there is an actual case or controversy between Counter-Defendants and Sarepta concerning the invalidity of the NS Patents. Counter-Defendants deny the remaining allegations in paragraph 78.

79. Sarepta is entitled to a declaratory judgment that the claims of the NS Patents are invalid.

ANSWER: Counter-Defendants deny the allegations of paragraph 79.

80. This case is exceptional and Sarepta is entitled to attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

ANSWER: Counter-Defendants deny the allegations of paragraph 80.

RESPONSES TO SAREPTA'S ALLEGATIONS REGARDING COUNTERCLAIM V (Breach of Contract)

81. Sarepta realleges each of the foregoing Paragraphs 1-80 as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference their answers to the allegations of Paragraphs 1-80 as if fully set forth herein.

82. Sarepta incorporates by reference its answers and responses to Nippon Shinyaku's Second Amended Complaint ("SAC") as if fully set forth herein.

ANSWER: Counter-Defendants incorporate by reference the Second Amended Complaint as if fully set forth herein.

83. Sarepta asserts a claim for breach of contract arising under Delaware state law. This Court has subject matter jurisdiction over this breach of contract claim under 28 U.S.C. §§ 1332(a) and 1367(a).

ANSWER: Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is required, Counter-Defendants admit that Sarepta's counterclaims purport to assert a breach of contract claim arising under Delaware state law. Counter-Defendants deny the remaining allegations in paragraph 83.

84. This claim for breach of contract arises out of Nippon Shinyaku's material breach of the MCA with Sarepta.

ANSWER: Counter-Defendants deny the allegations in paragraph 84.

85. Properly interpreted, the MCA is a valid and enforceable contract between Sarepta and Nippon Shinyaku.

ANSWER: Counter-Defendants admit that the MCA is a valid and enforceable contract between Sarepta and Nippon Shinyaku. Counter-Defendants deny any remaining allegations in paragraph 85.

86. Sections 1-3 of the MCA define "Confidential Information" and proscribe improper disclosures or uses of confidential information beyond the permitted purposes. Section 2.2, entitled "Obligations of Confidentiality and Non-Use," states among other relevant provisions that:

> The Parties intend and agree that this Agreement, the Proposed Transaction and all disclosures, including all meetings, discussions, correspondence, communications, documents, or other materials exchanged between the Parties made in connection with this Agreement and the Proposed Transaction shall not be submitted, referenced, admitted or otherwise used by the Recipient, its Affiliates, or their respective Representatives against the other Party in any legal action, except in an action to enforce the terms of this Agreement, and shall be treated as conducted in the aid of negotiation and shall be governed by and entitled to the protections and privileges of Delaware Rule of Evidence 408 and Federal Rule of Evidence 408, as well as any and all analogous or applicable privileges or additional limitations on use and disclosure set forth herein. Furthermore, regardless of whether the Proposed Transaction leads to any arrangement or resolution of issues, the fact that these confidential Proposed Transactions occurred shall not be referenced in any legal action currently pending, including but not limited to the EP Oppositions, the JP Actions, or the Potential Actions. Neither Party nor their Affiliates or Representatives shall in any way attempt to place into evidence any document, fact, statement or opinion in any way relating to the Proposed Transaction for any purpose, regardless of whether such document, fact, statement or opinion would be admissible under FRE 408 or any other analogous or applicable privilege.

ANSWER: Counter-Defendants admit that paragraph 86 recites a portion of Section 2.2 of the MCA. Counter-Defendants further admit that the term "Confidential Information" is listed in Section 1 of the MCA along with a definition of the term. Counter-Defendants also admit that the title of Section 2 of the MCA recites "Obligations of Confidentiality and Non-Use." Counter-Defendants deny the remaining allegations of paragraph 86.

87. On July 14, 2021, Nippon Shinyaku filed its original Complaint in this action containing confidential information in violation of its agreement, materially breaching its obligations under the MCA, Sections 1-3.

ANSWER: Counter-Defendants admit that Nippon Shinyaku filed its Original Complaint in this action on July 13, 2021. Counter-Defendants deny the remaining allegations of paragraph 87.

88. Notwithstanding that in its first set of Rule 12 responsive motions Sarepta raised its objection to such confidential information appearing in Nippon Shinyaku's original Complaint contrary to the terms of the MCA, Nippon Shinyaku again included the same confidential material in its First Amended Complaint ("FAC"), filed September 10, 2021 (D.I. 39).

ANSWER: Counter-Defendants admit that Nippon Shinyaku filed its First Amended Complaint on September 10, 2021. Counter-Defendants further admit that on September 3, 2021, Sarepta filed a Motion to Dismiss and Motion to Strike certain paragraphs of the Original Complaint. Counter-Defendants deny the remaining allegations of paragraph 88.

89. Sarepta renewed its objection in subsequent Rule 12 responsive motions (D.I. 53, 54) to such confidential information appearing in Nippon Shinyaku's FAC contrary to the terms of the MCA.

ANSWER: Counter-Defendants admit that Sarepta filed a Motion to Dismiss and Motion to Strike Portions of the First Amended Complaint on September 24, 2021. Counter-Defendants deny the remaining allegations of paragraph 89.

90. On December 20, 2021, the Court found that Nippon Shinyaku had violated the confidentiality and non-use provisions of the MCA and struck from the FAC the second sentence of paragraph 2 as well as paragraphs 11, 78, and 91 of the FAC. (Hearing Tr. at 31-34; D.I. 84.)

ANSWER: Counter-Defendants admit that the Court struck the second sentence of paragraph 2 and paragraphs 11, 78, and 91 of the First Amended Complaint. Counter-Defendants deny the remaining allegations of paragraph 90.

91. As the Court found, Nippon Shinyaku "agreed not to hold the parties' confidential communications against Sarepta in future litigation" because the terms of the valid and enforceable MCA had prohibitions against mentioning confidential communications in legal actions. *Id.* at 32, 34. But Nippon Shinyaku materially breached the terms of the agreement by including confidential information in its original Complaint and again in its FAC, even after being put on notice of its breach, requiring further briefing, motions practice, and a ruling by this Court striking the confidential information from Nippon Shinyaku's pleading.

ANSWER: Counter-Defendants admit that in the Hearing Transcript from the hearing on December 20, 2021, the Court stated that "NS agreed not to hold the parties' confidential

communications against Sarepta in future litigation." Counter-Defendants deny the remaining allegations of paragraph 91.

92. Sarepta has suffered prejudice and injury by virtue of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA's confidentiality and non-use provisions of Section 2, entitling Sarepta to damages in an amount exceeding $75,000.

ANSWER: Counter-Defendants deny the allegations of paragraph 92.

93. In addition, in view of Nippon Shinyaku's knowing and repeated bad-faith breaches of the MCA, Nippon Shinyaku has unclean hands precluding enforcement of the MCA and depriving it of any entitlement to injunctive or other equitable relief for any alleged breach of the MCA by Sarepta.

ANSWER: Counter-Defendants deny the allegations of paragraph 93.

GENERAL DENIAL

Except as expressly admitted in the preceding paragraphs above, Counter-Defendants deny each and every allegation of Sarepta's Counterclaims including, without limitation, the headings and subheadings contained in the Counterclaims. Pursuant to Rule 8(b) of the Federal Rules of Civil Procedure, allegations contained in the Counterclaims to which no responsive pleading is required and allegations for which Counter-Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations shall be deemed denied. Counter-Defendants expressly reserve the right to amend and/or supplement their answer.

RESPONSE TO SAREPTA'S PRAYER FOR RELIEF

Counter-Defendants deny that Sarepta is entitled to the relief it requests or to any other relief.

RESPONSE TO SAREPTA'S DEMAND FOR A JURY TRIAL

Counter-Defendants admit that Sarepta has demanded a jury trial for all triable issues alleged in its counterclaims but denies that a jury trial is warranted for Counterclaim V.

DEFENSES

Without assuming any burden other than those imposed by operation of law, and without admitting that they bear the burden of proof with respect to any of the following, Counter-Defendants, on information and belief, while reserving the right to add additional defenses based on facts learned in discovery or otherwise assert the following defenses.

First Defense
(Non-Infringement of the UWA Patents)

Counter-Defendants have not infringed and will not infringe, directly or indirectly, any valid and enforceable claim of the UWA Patents, either literally or under the doctrine of equivalents.

Second Defense
(Invalidity of the UWA Patents)

Each asserted claim of the UWA Patents is invalid for failure to comply with one or more requirements of the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

Third Defense
(Prosecution History Estoppel and Disclaimer)

Sarepta's claims that Counter-Defendants infringe the UWA Patents are estopped in whole, or in part, by representations made or actions taken during the prosecution of the applications that lead to the UWA Patents and/or related patents under the doctrine of prosecution history estoppel and/or prosecution history disclaimer.

Fourth Defense
(No Invalidity of the NS Patents)

All claims of the NS Patents are not invalid or unenforceable under 35 U.S.C. § 1 *et seq.*, and Sarepta will not be able to demonstrate otherwise by clear and convincing evidence.

Fifth Defense
(No Breach of Contract)

Counter-Defendants have not breached any contractual obligations under the MCA. To the extent Sarepta asserts a breach of contract claim against Counter-Defendant NS Pharma, NS Pharma was not a party to the MCA.

Sixth Defense
(Failure to State a Claim)

Sarepta's Counterclaims fail to state a claim upon which relief may be granted.

Seventh Defense
(Equitable Defenses and Remedies)

Sarepta's breach of contract claim and/or requested remedies arising from said breach of contract claim are barred in whole or in part under principles of equity, including unclean hands. By way of example only, in light of Sarepta's breach of the MCA by filing its IPR Petitions before the PTAB instead of challenging the validity of the NS Patents in the District of Delaware, Sarepta has unclean hands precluding it from enforcing the MCA and depriving it of any entitlement to injunctive or equitable relief for any alleged breach of the MCA by Counter-Defendants.

Eighth Defense
(No Damages)

Sarepta has not incurred any damages resulting from its allegations that Counter-Defendants have infringed the UWA Patents and/or breached the MCA. Counter-Defendants deny any allegations of infringement of the UWA Patents and breach of the MCA.

Ninth Defense
(Limitation on Damages and Costs)

Sarepta's claims for relief are barred in whole or in part, including without limitation by 35 U.S.C. §§ 286, 287, and/or 288.

Tenth Defense
(No Willful Infringement of the UWA Patents)

Counter-Defendants have not willfully infringed the UWA Patents, and Sarepta is therefore not entitled to enhanced damages pursuant to 35 U.S.C. § 284.

Eleventh Defense
(No Exceptional Case)

Sarepta cannot prove that its case against Counter-Claim Defendants is exceptional and warrants the award of attorney fees under 35 U.S.C. § 285 or pursuant to the Court's inherent power.

Reservation of Additional Defenses

Counter-Defendants reserve the right to add additional defenses based on facts learned in discovery or otherwise.

PRAYER FOR RELIEF

WHEREFORE, Counter-Defendants respectfully request the following relief:

A. A judgment in favor of Counter-Defendants with respect to Sarepta's Counterclaims;

B. A judgment that Sarepta is not entitled to any of the relief requested in its Counterclaims and dismissal of Sarepta's Counterclaims with prejudice;

C. A judgement declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Counter-Defendants their attorneys' fees;

D. A judgement awarding Counter-Defendants their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

E. Such other and further relief as the Court may deem just and proper.

Dated: February 18, 2022

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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Attorneys for Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.

Exhibit IV

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015-GBW JURY TRIAL DEMANDED
SAREPTA THERAPEUTICS, INC., Defendant and Counter-Plaintiff, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff and Counter-Defendants.	

[PROPOSED] SCHEDULING ORDER [PATENT, NON-ANDA]

This 12th day of December, 2022, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five (5) days of the date the Court enters this Order. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at http://www.ded.uscourts.gov (*see* Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **March 23, 2023**. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 4(g) and 5.

3. Disclosures. Absent agreement among the parties, and approval of the Court:

(a) By **April 18, 2022**, Plaintiff and Counterclaim-Plaintiff shall identify the accused product(s), including accused methods and systems, and its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s). Plaintiff and Counterclaim-Plaintiff shall also produce the file history for each asserted patent.

(b) By **May 18, 2022**, Defendant and Counterclaim-Defendants shall produce core technical documents related to the accused product(s), sufficient to show how the accused product(s) work(s), including but not limited to non-publicly available operation manuals, product literature, schematics, and specifications. Defendant and Counterclaim-Defendants shall also produce sales figures for the accused product(s).

(c) By **June 17, 2022**, Plaintiff and Counterclaim-Plaintiff shall produce an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes.

(d) By **July 18, 2022**, Defendant and Counterclaim-Defendants shall produce its initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

(e) By **June 22, 2023**, Defendant and Counterclaim-Plaintiff shall provide final infringement contentions.

(f) By **July 11, 2023**, Defendant and Counterclaim-Defendants shall provide final invalidity contentions.

(g) By **July 11, 2023,** Defendant and Counterclaim-Defendants shall provide final non-infringement contentions.

(h) By **July 20, 2023**, Plaintiff and Counterclaim-Plaintiff shall provide final validity contentions.

4. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules of Civil Procedure shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **July 27, 2023.**

(b) Document Production. Document production shall be substantially complete by **January 20, 2023**.

(c) Requests for Admission. A maximum of **60** requests for admission are permitted for each side. Requests for admission that are limited only to authentication of documents shall not be counted against this limit.

(d) Interrogatories.

i. A maximum of **35** interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof.

The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of **100** hours of taking testimony by deposition upon oral examination. For any witness who testifies in a foreign language with an interpreter, each two hours of deposition testimony shall be counted as **one hour and 15 minutes**.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. The parties will meet and confer about any restrictions on location and procedures for depositions in view of the COVID-19 pandemic and travel conditions.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **August 14, 2023**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **September 11, 2023**. Reply expert reports from the party with the initial burden of proof are due on or before **October 2, 2023**. No other expert reports will be permitted without either the consent of all

parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.

iii. Expert Discovery Cut-Off. All expert discovery in this case shall be initiated so that it will be completed on or before **October 30, 2023**.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts - including verbal communications among Delaware and Lead Counsel for all parties to the dispute - that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

> Dear Judge Williams:
>
> The parties in the above-referenced matter write to request the scheduling of a discovery teleconference.
>
> The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s): _____

Delaware Counsel: _____

Lead Counsel: _____

The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

5. Motions to Amend.

(a) Any motion to amend (including a motion for leave to amend) a pleading shall ***NOT*** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

6. Motions to Strike.

(a) Any motion to strike any pleading or other document shall ***NOT*** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

7. Technology Tutorials. By **January 17, 2023**, the parties jointly shall provide the Court, a tutorial on the technology at issue. In that regard, the parties shall jointly submit to the Court an electronic tutorial of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and educate the Court about the same and should not be used for argument. As to the format selected, the parties should confirm the Court's technical abilities to access the

information contained in the tutorial ("mpeg", "quicktime", etc.). The parties may choose to file their tutorial under seal, subject to any protective order in effect.

8. Claim Construction Issue Identification. On or before **October 26, 2022**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). On or before **November 22, 2022**, the parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **December 15, 2022**. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to gbw_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

9. Claim Construction Briefing. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, their opening brief, not to exceed 5,000 words, on **January 5, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file, their answering brief not to exceed 7,500 words, on **February 6, 2023**. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, their reply brief, not to exceed 5,000 words, on **February 27, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file their sur-reply brief, not to exceed 2,500 words, on **March**

13, 2023. No later than **March 20, 2023**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

The parties may file separate joint claim construction briefs for terms applicable to the patents asserted by Plaintiff and by Counterclaim-Plaintiff. However, the parties shall meet and confer to ensure that the parties request that the Court construe no more than twelve (12) terms across the two joint claim construction briefs.

10. Hearing on Claim Construction. Beginning at **10 a.m.** on **April 19, 2023**, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

11. Interim Status Report. On **February 23, 2023**, counsel shall submit a joint letter to the Court with an interim report of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

12. Supplementation. Absent agreement among the parties, and approval of the Court,

(a) no later than **June 22, 2023** the Plaintiff and Counterclaim-Plaintiff must finally supplement the identification of all accused products and serve final infringement contentions; and

(b) no later than **July 11, 2023** the accused infringers must finally supplement the identification of all invalidity references and serve final invalidity contentions.

13. Case Dispositive Motions.

(a) All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before **November 20, 2023**. Answering case dispositive motion briefs shall be filed on or before **December 15, 2023**. Reply case dispositive motion briefs shall be filed on or before **January 10, 2024**. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date for opening dispositive motions and briefs without leave of the Court.

(b) Concise Statement of Facts Requirement. Any motion for summary judgment shall be accompanied by a separate concise statement, not to exceed six (6) pages, which details each material fact which the moving party contends is essential for the Court's resolution of the summary judgment motion (not the entire case) and as to which the moving party contends there is no genuine issue to be tried. Each fact shall be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

Any party opposing the motion shall include with its opposing papers a response to the moving party's concise statement, not to exceed six (6) pages, which admits or disputes the facts set forth in the moving party's concise statement on a paragraph-by-paragraph basis. To the extent a fact is disputed, the basis of the dispute shall be supported by specific citation(s) to the record. Failure to respond to a fact presented in the moving party's concise statement of facts shall indicate that fact is not in dispute for purposes of summary judgment. The party opposing the motion may also include with its opposing papers a separate concise statement, not to exceed four (4) pages, which sets forth material facts as to which the opposing party contends there is a genuine issue to be tried. Each fact asserted by the opposing party shall also be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

The moving party shall include with its reply papers a response to the opposing party's concise statement of facts, not to exceed four (4) pages, on a paragraph-by-paragraph basis. Failure to respond to a fact presented in the opposing party's concise statement of facts shall indicate that fact remains in dispute for purposes of summary judgment.

(c) Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired provided, however, that each ***SIDE*** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each ***SIDE***.[1]

(d) Ranking of Summary Judgment Motions. Any party that files more than one summary judgment motion shall number each motion to indicate the order in which the party wishes the Court to review its pending motions. The first motion the party wishes the Court to consider shall be designated #1, the second motion shall be designated #2, and so on. The Court will review the party's summary judgment motions in the order designated by the party. If the Court decides to deny a motion filed by the party, barring exceptional reasons determined *sua sponte* by the Court, the Court will not review any lower ranked summary judgment motions filed by the party.

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[1] The parties must work together to ensure that the Court receives no more than a total of 250 pages (i.e., 50 + 50 + 25 regarding one side's motions, and 50 + 50 + 25 regarding the other side's motions) of briefing on all case dispositive motions and Daubert motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

14. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

15. Application to Court for Protective Order. A Stipulated Protective Order was entered by the Court on June 21, 2022.

16. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

17. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of filings (*i.e.*, briefs, appendices, exhibits, declarations, affidavits etc.). Courtesy copies of appendices and exhibits should include hard tabs. This provision also applies to papers filed under seal.

18. Motions in *Limine*. Motions in *limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered

by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

19. Pretrial Conference. On **May 6, 2024**, the Court will hold a pretrial conference in Court with counsel beginning at **4:30 p.m**. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

20. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms seven (7) business days before the final pretrial conference. This submission shall be accompanied by a courtesy copy containing electronic files of these documents, in Microsoft Word format, which may be submitted by e-mail to gbw_civil@ded.uscourts.gov.

21. Trial. This matter is scheduled for a **seven** (7) day jury trial beginning at 9:30 a.m. on **May 13, 2024**, with the subsequent trial days beginning at 9:30 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 5:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

22. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

23. Post-Trial Motions. Unless otherwise ordered by the Court, all ***SIDES*** are limited to a maximum of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.

24. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

The Honorable Gregory B. Williams
United States District Judge

CHART OF RELEVANT DATES[2]

EVENT	DEADLINE
Parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. (¶ 8)	November 22, 2022
Filing of Joint Claim Construction Chart (¶ 9)	December 15, 2022
Plaintiffs' Opening Claim Construction Brief & Counter-Claim Plaintiffs' Opening Claim Construction Brief (¶ 9)	January 5, 2023
Deadline to Submit Joint Technology Tutorial (¶ 7)	January 17, 2023
Substantial Completion of Document Production (¶ 4(b))	January 20, 2023
Defendants' Answering Claim Construction Brief & Counterclaim-Claim Defendants' Answering Claim Construction Brief (¶ 9)	February 6, 2023
Interim Status Report (¶11)	February 23, 2023
Plaintiffs' Reply Claim Construction Brief & Counterclaim-Plaintiffs' Reply Claim Construction Brief (¶ 9)	February 27, 2023

[2] Dates which have already passed and were set forth in the previous Scheduling Order (D.I. 124) are omitted from the chart.

EVENT	DEADLINE
Defendant's Sur-Reply Claim Construction Brief & Counterclaim-Defendants' Reply Claim Construction Brief (¶ 9)	March 13, 2023
Filing of Joint Claim Construction Briefs (¶ 9)	March 20, 2023
Last Day to Join Other Parties and to Amend the Pleadings (¶ 2)	March 23, 2023
Claim Construction Hearing (¶ 10)	April 19, 2023
Deadline for Plaintiffs & Counterclaim-Plaintiff to Supplement Identification of All Accused Products (¶ 12a)	June 22, 2023
Plaintiffs & Counterclaim Plaintiff to Provide Final Infringement Contentions (¶ 12a)	June 22, 2023
Deadline for Defendants & Counterclaim-Defendants to Supplement Invalidity References (¶ 12b)	July 11, 2023
Defendant & Counterclaim-Defendants to Provide Final Invalidity Contentions (¶ 7f)	July 11, 2023
Defendant & Counterclaim-Defendants to Provide Final Non-Infringement Contentions (¶ 3g)	July 11, 2023
Plaintiff & Counterclaim-Plaintiff to Provide Final Validity Contentions (¶ 7h)	July 20, 2023

EVENT	DEADLINE
Fact Discovery Cut Off (¶ 4a)	July 27, 2023
Opening Expert Reports (¶ 4f)	August 14, 2023
Rebuttal Expert Reports (¶ 4f)	September 11, 2023
Reply Expert Reports (¶ 4f)	October 2, 2023
Close of Expert Discovery (¶ 4f)	October 30, 2023
Case Dispositive Motions (Opening Briefs) (¶13a)	November 20, 2023
Answering Case Dispositive Briefs (¶13a)	December 15, 2023
Reply Case Dispositive Briefs (¶13a)	January 10, 2024
Deadline to File Proposed Voir Dire, Preliminary Jury Instructions, and Final Jury Instructions (¶ 20)	7 days before Pretrial Conference
Deadline to File Joint Proposed Final Pretrial Order (¶ 19)	7 days before Pretrial Conference
Pretrial Conference (¶ 19)	May 6, 2024
Trial (7-day jury) (¶ 21)	May 13, 2024